



# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: SB 152**

**VERSION: AMENDED APRIL 18, 2005**

**AUTHOR: SPEIER**

**SPONSOR: SPEIER**

**RECOMMENDED POSITION: OPPOSE**

**SUBJECT: PSEUDOEPHEDRINE**

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### **Existing Law:**

- 1) It unlawful for a manufacturer, wholesaler, retailer, or other person to sell, transfer or furnish pseudoephedrine to a person under 18 years of age. (H&S 11100(g)(1))
- 2) It unlawful for a person under 18 years of age to possess pseudoephedrine. (H&S 11100(g)(2))
- 3) It is unlawful for a retail distributor to sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids. (H&S 11100(g)(3))

### **This Bill:**

- 1) Deletes B&P 405.1 provisions of the previous versions of the bill and replaces them with new H&S 11100.02 provisions.
- 2) Adds H&S 11100.02 Section 1 and states Section 1 will become operative on June 1, 2006, and will remain in effect only until January 1, 2008; Section 2 would become operative January 1, 2008.

### **Section 1**

- a. Requires a pharmacist and a retail distributor to store products containing any amount of pseudoephedrine or the salts, isomers, or salts of isomers of pseudoephedrine [product] in a locked area.
- b. Prohibits a pharmacy and a retail distributor from selling a product to a purchaser unless the purchaser presents a valid, current identification that contains a photo of himself or herself and that was issued by a governmental agency.
- c. Requires staff members of a retail distributor to receive training in the following areas before they are permitted to sell product:
  - i. Identification of pseudoephedrine products.
  - ii. Usage of pseudoephedrine in manufacturing methamphetamine.

- d. Makes a first violation of the provisions of the bill a misdemeanor and subsequent violations punishable by imprisonment in a county jail not exceeding one year, a fine not exceeding ten thousand dollars (\$10,000), or by both the fine and imprisonment.
  - e. Exempts the following products from the provisions of the bill: a compound, mixture, or preparation of pseudoephedrine that is in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient; a pediatric liquid.
- 3) Adds H&S 11100.02 Section 2 and states Section 2 shall become operative on January 1, 2008.
- 4) Repeats the requirements in Section 1 and adds the following requirements:
- a. Requires a pharmacist and a retail distributor, to record the following information prior selling a product:
    - i. The date of purchase.
    - ii. The name and address of the purchaser.
    - iii. The number of the identification presented by the purchaser.
    - iv. The name and amount of the product that is purchased.
  - b. Requires a pharmacy and retail distributor to maintain the record for at least three years from the product's date of purchase in an electronic format approved by the AG.
  - c. Restricts the sale of product to no more than three packages or more than nine grams of the product within any 30-day period to a single purchaser.
  - d. Requires a pharmacist and a retail distributor to develop a system that notifies the pharmacist or retail distributor when a purchaser's limit has been reached.

(H&S 11100.02 Added)

**Comment:**

**1) Author's Intent.** The author is seeking to limit the supply of pseudoephedrine available for illegal methamphetamine (meth) production, while making the product reasonably accessible for legitimate use.

**2) Enforcement.** The April 18<sup>th</sup> version of the bill takes the provisions of the bill out of the Pharmacy Law and places them in the H&S Code. Consequently, the board would not be responsible for enforcing the measure.

**3) Retail Chains' Voluntary Efforts.** In an effort to combat illegal methamphetamine production, the following major drug retailers have voluntarily agreed to move all single ingredient pseudoephedrine products behind the pharmacy counter: Albertsons, CVS, Longs Drugs, Kmart, Rite Aid, Shopko, Target, Walgreens, and Wal-mart. Additionally, the National Association of Chain Drug Stores, which represents more than 36,000 pharmacies, supports federal legislation (S 103) to reduce access to pseudoephedrine products, including requiring the sale of pseudoephedrine products behind the pharmacy counter by a licensed pharmacist or pharmacy personnel.

**4) State Legislation.** AB 283 (Koretz), Pseudoephedrine: retail sale, is similar to SB 152 in its attempt to restrict the sale of pseudoephedrine for illegal uses. AB 283 would limit access to ephedrine and pseudoephedrine products by requiring 1) the products to be placed in a locked cabinet, and 2) a retail employee check the identification of a purchaser and report specified information about purchases to the DOJ. AB 283 would place these provisions in H&S 11100.01.

Development Committee on June 27, 2005; the measure was granted reconsideration, but has not been rescheduled for a hearing.

AB 162 (Runner 1999, C. 978) made it a misdemeanor for any retail distributor to sell more than 3 packages of a product that contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or more than 9 grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in a single transaction.

**5) Federal Legislation.** In January 2005, S103 and HR 314, the Combat Meth Act of 2005, were introduced in Congress. Each of these measures contains provisions similar to those in SB 283. Both Federal measures are waiting to be heard in committee.

## **6) History.**

2005

May 2	Reconsideration granted.
Apr. 25	Set, final hearing. Failed passage in committee. (Ayes 3. Noes 3. Page 768.)
Apr. 18	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Apr. 11	Set, second hearing. Hearing canceled at the request of author. Set for hearing April 25.
Apr. 4	Set, first hearing. Hearing canceled at the request of author. Set for hearing April 18.
Mar. 23	Set for hearing April 11.
Feb. 24	To Com. on B., P. & E.D.
Feb. 8	From print. May be acted upon on or after March 10.
Feb. 7	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN ASSEMBLY JUNE 15, 2005

AMENDED IN SENATE MAY 4, 2005

AMENDED IN SENATE APRIL 12, 2005

AMENDED IN SENATE APRIL 4, 2005

**SENATE BILL**

**No. 401**

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**Introduced by Senator Ortiz**

February 17, 2005

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An act to amend Section 56.05 of the Civil Code, relating to medical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 401, as amended, Ortiz. Medical information: pharmacies: marketing.

Existing law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and, if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor. Existing law provides that this prohibition also applies to the marketing of medical information, as defined, excluding from that definition, for these purposes, communications for which the communicator does not receive remuneration from a 3rd party or for specified descriptive purposes, or that are tailored to the circumstances of a particular individual, as specified.

This bill would further provide that marketing includes a written communication that is provided by a pharmacy to a patient about a different drug or treatment than that being dispensed by the pharmacy and that is paid for, or sponsored by, a manufacturer, labeler, or distributor of prescription drugs, except as specified. Because a violation thereof may be punishable as a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. Section 56.05 of the Civil Code is amended to
- 2 read:
- 3 56.05. For purposes of this part:
- 4 (a) "Authorization" means permission granted in accordance
- 5 with Section 56.11 or 56.21 for the disclosure of medical
- 6 information.
- 7 (b) "Authorized recipient" means any person who is
- 8 authorized to receive medical information pursuant to Section
- 9 56.10 or 56.20.
- 10 (c) "Contractor" means any person or entity that is a medical
- 11 group, independent practice association, pharmaceutical benefits
- 12 manager, or a medical service organization and is not a health
- 13 care service plan or provider of health care. "Contractor" does
- 14 not include insurance institutions as defined in subdivision (k) of
- 15 Section 791.02 of the Insurance Code or pharmaceutical benefits
- 16 managers licensed pursuant to the Knox-Keene Health Care
- 17 Service Plan Act of 1975 (Chapter 2.2 (commencing with
- 18 Section 1340) of Division 2 of the Health and Safety Code).
- 19 (d) "Health care service plan" means any entity regulated
- 20 pursuant to the Knox-Keene Health Care Service Plan Act of
- 21 1975 (Chapter 2.2 (commencing with Section 1340) of Division
- 22 2 of the Health and Safety Code).

1 (e) “Licensed health care professional” means any person  
2 licensed or certified pursuant to Division 2 (commencing with  
3 Section 500) of the Business and Professions Code, the  
4 Osteopathic Initiative Act or the Chiropractic Initiative Act, or  
5 Division 2.5 (commencing with Section 1797) of the Health and  
6 Safety Code.

7 (f) (1) “Marketing” means to make a communication about a  
8 product or service that encourages recipients of the  
9 communication to purchase or use the product or service.

10 (2) “Marketing” does not include any of the following:

11 (A) Communications made orally or in writing for which the  
12 communicator does not receive direct or indirect remuneration,  
13 including, but not limited to, gifts, fees, payments, subsidies, or  
14 other economic benefits, from a third party for making the  
15 communication.

16 (B) Communications made to current enrollees solely for the  
17 purpose of describing a provider’s participation in an existing  
18 health care provider network or health plan network of a  
19 Knox-Keene licensed health plan to which the enrollees already  
20 subscribe; communications made to current enrollees solely for  
21 the purpose of describing if, and the extent to which, a product or  
22 service, or payment for a product or service, is provided by a  
23 provider, contractor, or plan or included in a plan of benefits of a  
24 Knox-Keene licensed health plan to which the enrollees already  
25 subscribe; or communications made to plan enrollees describing  
26 the availability of more cost-effective pharmaceuticals.

27 (C) Communications that are tailored to the circumstances of a  
28 particular individual to educate or advise the individual about  
29 treatment options, and otherwise maintain the individual’s  
30 adherence to a prescribed course of medical treatment, as  
31 provided in Section 1399.901 of the Health and Safety Code, for  
32 a chronic and seriously debilitating or life-threatening condition  
33 as defined in subdivisions (d) and (e) of Section 1367.21 of the  
34 Health and Safety Code, if the health care provider, contractor, or  
35 health plan receives direct or indirect remuneration, including,  
36 but not limited to, gifts, fees, payments, subsidies, or other  
37 economic benefits, from a third party for making the  
38 communication, if all of the following apply:

39 (i) The individual receiving the communication is notified in  
40 the communication in typeface no smaller than 14-point type of

1 the fact that the provider, contractor, or health plan has been  
2 remunerated and the source of the remuneration.

3 (ii) The individual is provided the opportunity to opt out of  
4 receiving future remunerated communications.

5 (iii) The communication contains instructions in typeface no  
6 smaller than 14-point type describing how the individual can opt  
7 out of receiving further communications by calling a toll-free  
8 telephone number of the health care provider, contractor, or  
9 health plan making the remunerated communications. No further  
10 communication may be made to an individual who has opted out  
11 after 30 calendar days from the date the individual makes the opt  
12 out request.

13 (3) ~~“Marketing”~~ *Notwithstanding any other provision of law,*  
14 *“marketing”* includes a written communication that is provided  
15 to a pharmacy patient by a pharmacist or by pharmacy personnel,  
16 in conjunction with the dispensing of a prescription drug or  
17 prescribed treatment therapy, that includes the trade name or  
18 commercial slogan for any prescription drug, prescribed  
19 treatment therapy, or over-the-counter medication other than the  
20 prescription drug or prescribed treatment therapy being  
21 dispensed, if the communication is paid for or sponsored, directly  
22 or indirectly, by a manufacturer, labeler, or distributor of  
23 prescription drugs. This paragraph shall not apply when a trade  
24 name or commercial slogan for a prescription drug, prescribed  
25 treatment therapy, or over-the-counter medication is included in  
26 a written communication for the sole purpose of ~~identifying a~~  
27 ~~potential adverse drug interaction with the prescription drug or~~  
28 ~~prescribed treatment therapy being dispensed.~~ *providing*  
29 *information about drug interactions, reported or potential*  
30 *adverse events, or any other information necessary to ensure the*  
31 *health and safety of the patient, or is part of a package insert that*  
32 *has been approved by the federal Food and Drug Administration*  
33 *to be distributed together with a prescription drug.*

34 (g) “Medical information” means any individually identifiable  
35 information, in electronic or physical form, in possession of or  
36 derived from a provider of health care, health care service plan,  
37 pharmaceutical company, or contractor regarding a patient’s  
38 medical history, mental or physical condition, or treatment.  
39 “Individually identifiable” means that the medical information  
40 includes or contains any element of personal identifying

1 information sufficient to allow identification of the individual,  
2 such as the patient's name, address, electronic mail address,  
3 telephone number, or social security number, or other  
4 information that, alone or in combination with other publicly  
5 available information, reveals the individual's identity.

6 (h) "Patient" means any natural person, whether or not still  
7 living, who received health care services from a provider of  
8 health care and to whom medical information pertains.

9 (i) "Pharmaceutical company" means any company or  
10 business, or an agent or representative thereof, that manufactures,  
11 sells, or distributes pharmaceuticals, medications, or prescription  
12 drugs. "Pharmaceutical company" does not include a  
13 pharmaceutical benefits manager, as included in subdivision (c),  
14 or a provider of health care.

15 (j) "Provider of health care" means any person licensed or  
16 certified pursuant to Division 2 (commencing with Section 500)  
17 of the Business and Professions Code; any person licensed  
18 pursuant to the Osteopathic Initiative Act or the Chiropractic  
19 Initiative Act; any person certified pursuant to Division 2.5  
20 (commencing with Section 1797) of the Health and Safety Code;  
21 any clinic, health dispensary, or health facility licensed pursuant  
22 to Division 2 (commencing with Section 1200) of the Health and  
23 Safety Code. "Provider of health care" does not include  
24 insurance institutions as defined in subdivision (k) of Section  
25 791.02 of the Insurance Code.

26 SEC. 2. No reimbursement is required by this act pursuant to  
27 Section 6 of Article XIII B of the California Constitution because  
28 the only costs that may be incurred by a local agency or school  
29 district will be incurred because this act creates a new crime or  
30 infraction, eliminates a crime or infraction, or changes the  
31 penalty for a crime or infraction, within the meaning of Section  
32 17556 of the Government Code, or changes the definition of a  
33 crime within the meaning of Section 6 of Article XIII B of the  
34 California Constitution.





# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: SB 401**

**VERSION: AMENDED JUNE 15, 2005**

**AUTHOR: ORTIZ**

**SPONSOR: CA. PUBLIC INTEREST  
RESEARCH GROUP**

**RECOMMENDED POSITION: NONE**

**SUBJECT: MEDICAL INFORMATION: PHARMACIES: MARKETING**

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### Existing Law:

- 1) Defines marketing as "communication about a product or service that encourages recipients of the communication to purchase or use the product or service."
- 2) Excludes the following from the definition of marketing:
  - a. Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration from a third party for making the communication.
  - b. Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe
  - c. Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment for a chronic and seriously debilitating or life-threatening condition, if the health care provider, contractor, or health plan receives direct or indirect remuneration from a third party for making the communication, if all of the following apply:
    - i. The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.
    - ii. The individual is provided the opportunity to opt out of receiving future remunerated communications.
    - iii. The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free number of the health care provider, contractor, or health plan making the remunerated communications.

(Civil Code 56.05)

## **This Bill:**

Defines “marketing” to include a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription drug or prescribed treatment therapy, that includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription drug or prescribed treatment therapy being dispensed, if the:

1. The communication describes includes the name of, or describes biochemical, pharmacological, or other scientific or health information for, any other drug or treatment other than the drug or treatment being dispensed; and
2. The communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs.

Specifies that this definition does not apply when 1) a trade name or commercial slogan for a prescription drug, prescribed treatment therapy, or 2) over-the-counter medication is included in a written communication for the sole purpose of providing information about drug interactions, reported or potential adverse events, or any other information necessary to ensure the health and safety of the patient, or is part of a package insert that has been approved by the federal Food and Drug Administration to be distributed together with a prescription drug.

(Civil Code 56.05 Amended)

## **Comment:**

**1) Author’s Intent.** The author’s intent is to close a loophole that she sees in the law that allows drug manufacturers to distribute biased written information to patients through pharmacists during face-to-face drug consultations. An example would be an pharmacist giving a patient an advertisement, during the face to face consultation, that list other possible drugs that could be taken for the same condition.

**2) Background.** AB 715 (Chan, Chapter 562, Statutes of 2003), sought to prohibit marketing practices where a health care provider or entity was paid to market a third party’s product or service to a patient, using that patient’s medical information. While the bill protected consumer privacy, it did not completely deal with issues surrounding third party marketing to consumers. The question arises, does permitting drug companies to pay for advertising or the production of fact sheets used by pharmacists in consultations with patients benefit or harm the consumer?

AB 746 (Mathews, 2003) was proposed as “clean-up” legislation to AB 715. AB 746 would have clarified that pharmacists had the right to provide patient pamphlets with drug manufacture advertising or messages that informed patients of about the drug they were receiving. Pharmacists argued that including advertisements helped pay for the costs of producing the pamphlets and that prohibiting advertising would result in patients receiving less information about the drug they are taking. AB 746 died in the Senate.

Likewise, SB 401 is also being proposed as “clean-up” legislation to AB 715, but unlike AB 746, it takes the position that marketing information from drug manufacturers during face-to-face interaction is bad for the consumer and should therefore be prohibited. Supporters of the measure argue that information from pharmacists should be free from bias and information from drug manufacturers may confuse patients and contradict the information they receive from their doctor.

## **3) Previous Legislation.**

AB 715 (Chan, Chapter 562, Statutes of 2003) Personal Information.

#### 4) Support & Opposition

Support: California Public Interest Research Group (sponsor)  
California Alliance for Retired Americans  
California Labor Federation  
Consumers Union

Opposition: The Body  
CA Pharmacists Association  
CA Retailers Association  
Catalina Health Resource; Kaiser Permanente  
Nat'l Association of Chain Drug Stores  
Nat'l Consumers League  
Nat'l Council on Patient Information and Education  
Novartis Pharmaceuticals  
Pharmaceutical Research and Manufacturers of America  
Rite Aid

#### 5) History.

2005  
June 28 Set, first hearing. Hearing canceled at the request of author.  
June 15 From committee with author's amendments. Read second time. Amended. Re-referred to committee.  
June 13 To Coms. on HEALTH and JUD.  
May 26 In Assembly. Read first time. Held at Desk.  
May 26 Read third time. Passed. (Ayes 23. Noes 13. Page 1190.) To Assembly.  
May 25 Read second time. To third reading.  
May 24 From committee: Be placed on second reading file pursuant to Senate Rule 28.8.  
May 16 Set for hearing May 23.  
May 4 Read second time. Amended. Re-referred to Com. on APPR.  
May 3 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 5. Noes 2. Page 801.)  
Apr. 14 Set for hearing April 26.  
Apr. 12 Read second time. Amended. Re-referred to Com. on JUD.  
Apr. 11 From committee: Do pass as amended, but first amend, and re-refer to Com. on JUD. (Ayes 8. Noes 3. Page 498.)  
Apr. 4 From committee with author's amendments. Read second time. Amended. Re-referred to committee.  
Mar. 16 Set for hearing April 6.  
Feb. 24 To Coms. on HEALTH and JUD.  
Feb. 18 From print. May be acted upon on or after March 20.  
Feb. 17 Introduced. Read first time. To Com. on RLS. for assignment. To print.

**Introduced by Senator Aanestad**

February 18, 2005

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An act to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy technicians.

LEGISLATIVE COUNSEL'S DIGEST

SB 592, as amended, Aanestad. Acute care hospitals: inpatient pharmacy technician services.

Existing law, the Pharmacy Law, provides for the regulation of the practice of pharmacy by the California State Board of Pharmacy, in the Department of Consumer Affairs. Existing law authorizes a registered pharmacy technician to assist in the performance of pharmacy related duties under the supervision of a licensed pharmacist. A violation of the Pharmacy Law is a crime.

This bill would authorize a general acute care hospital to implement a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for certain patients, if specified requirements are met. *The bill would require a hospital that operates this program to keep a list of all qualified pharmacy technicians available for board inspection and to keep all required data in the hospital for at least 3 years.*

Because a failure to meet the training *and other* requirements in this bill would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1     *SECTION 1. The Legislature finds and declares all of the*  
2     *following:*

3     *(a) Pharmacists have emerged as critical members of a*  
4     *medical team by providing services such as patient education,*  
5     *drug therapy monitoring, and pharmacokinetic consultations.*  
6     *Pharmacists often work side by side with physicians and nurses,*  
7     *and participate in medical rounds. Pharmacists play an integral*  
8     *role in ensuring a safe medication use process. Through*  
9     *interpretation, evaluation, and clarification of orders,*  
10    *pharmacists ensure the absence of drug allergies, interactions,*  
11    *duplications, and the optimal selection of dose, dosage form,*  
12    *frequency, route, and duration of therapy.*

13    *(b) There currently exists a shortage of pharmacists in the*  
14    *state, and this shortage has the potential to cause harm to*  
15    *patients because hospitals lack sufficient staffing to fully take*  
16    *advantage of clinical pharmacy programs that have been shown*  
17    *to reduce the number of medication errors in hospitals and*  
18    *improve patient outcomes.*

19    *(c) Studies authorized by the California State Board of*  
20    *Pharmacy, and conducted under the direction of the University*  
21    *of California, San Francisco, at major California hospitals, have*  
22    *established that certain nondiscretionary functions currently*  
23    *performed by pharmacists in the hospital setting can safely be*  
24    *performed by properly trained pharmacy technicians.*  
25    *Specifically, allowing properly trained pharmacy technicians to*  
26    *check certain tasks performed by other pharmacy technicians is*  
27    *a safe and efficient use of staff, and frees pharmacists to provide*  
28    *the more important and skilled clinical pharmacy services that*  
29    *are critical to quality patient care and the reduction of*  
30    *medication errors.*

1 (d) Pharmacists are substantially over-qualified for  
2 performing these nondiscretionary inpatient checking functions,  
3 and current rules that require pharmacists to perform these  
4 functions unnecessarily limit hospitals in their capacity to fully  
5 provide patients with clinical pharmacy services.

6 (e) It is the intent of the Legislature in enacting this act that  
7 pharmacists remain responsible for pharmacy operations.  
8 Nothing in these provisions should be interpreted to eliminate or  
9 minimize the role of pharmacists in directly supervising  
10 pharmacy technicians and pharmacy operations. It is the further  
11 intent of the Legislature that hospitals take advantage of the  
12 efficiencies created by these provisions by using properly trained  
13 pharmacy technicians for certain nondiscretionary checking  
14 functions and more completely utilize the training and skills of  
15 their pharmacist staff to implement and expand clinical  
16 pharmacy programs at their facilities.

17 SECTION 1.

18 SEC. 2. Article 7.6 (commencing with Section 4128) is added  
19 to Chapter 9 of Division 2 of the Business and Professions Code,  
20 to read:

21  
22 Article 7.6. Inpatient Pharmacy Technician Services  
23

24 ~~4128. Notwithstanding any other provision of this chapter or~~  
25 ~~any other provision of law, a general acute care hospital, as~~  
26 ~~defined in subdivision (a) of Section 1250 of the Health and~~  
27 ~~Safety Code, may implement and operate a program utilizing~~  
28 ~~specially trained pharmacy technicians to check the work of other~~  
29 ~~pharmacy technicians in connection with the filling of floor and~~  
30 ~~ward stock and unit dose distribution systems for patients~~  
31 ~~admitted to the hospital whose orders have previously been~~  
32 ~~reviewed by a licensed pharmacist. A hospital implementing and~~  
33 ~~operating a program pursuant to this section shall meet all of the~~  
34 ~~following requirements:~~

35 ~~(a) The hospital shall conduct a special training program for~~  
36 ~~technicians who perform the checking function that provides the~~  
37 ~~technicians with the same training that a pharmacist would be~~  
38 ~~provided with under paragraph (1) of subdivision (b) of Section~~  
39 ~~4052.~~

1     ~~(b) The hospital shall conduct a continuous quality~~  
2     ~~improvement program.~~

3     ~~(c) The hospital shall establish and maintain a program~~  
4     ~~utilizing pharmacists to provide clinical services, as described in~~  
5     ~~Section 4052.~~

6     ~~(d) The hospital shall have a current, nonprovisional,~~  
7     ~~noneconditional accreditation from the Joint Commission on the~~  
8     ~~Accreditation of Healthcare Organizations or another nationally~~  
9     ~~recognized accrediting organization.~~

10     4128. (a) Notwithstanding any other provision of law, a  
11     general acute care hospital, as defined in subdivision (a) of  
12     Section 1250 of the Health and Safety Code, may implement and  
13     operate a program utilizing specially trained pharmacy  
14     technicians to check the work of other pharmacy technicians in  
15     connection with the filling of floor and ward stock and unit dose  
16     distribution systems for patients admitted to the hospital whose  
17     orders have previously been reviewed by a licensed pharmacist.  
18     The hospital may implement and operate this type of a program  
19     if all of the following requirements are met:

20     (1) The hospital conducts a special training program for  
21     technicians who perform the checking function that satisfies the  
22     requirements of subdivision (b).

23     (2) The hospital conducts a continuous quality improvement  
24     program that, at a minimum, audits the performance of the  
25     specially trained pharmacy technicians at least every three  
26     months for the first year, and annually thereafter. A pharmacy  
27     technician whose audited accuracy rate falls below 99.8 percent  
28     shall not be permitted to check the work of other pharmacy  
29     technicians until he or she is requalified pursuant to paragraph  
30     (1).

31     (3) The hospital has a current nonprovisional, nonconditional  
32     accreditation from the Joint Commission on the Accreditation of  
33     Healthcare Organizations or another nationally recognized  
34     accrediting organization.

35     (4) The hospital pharmacy has been inspected by the board.

36     (5) The hospital establishes and maintains a program utilizing  
37     pharmacists to provide clinical services as described in Section  
38     4052.

39     (b) The training program required by paragraph (1) of  
40     subdivision (a) shall include both didactic and practical

1 *elements, and shall specify requirements to be completed prior to*  
2 *the technician commencing participation in the checking*  
3 *program.*

4 *(1) The didactic component of the training shall consist of at*  
5 *least four hours of education covering the following topics:*

6 *(A) Information required to be on the label of unit dose or*  
7 *extemporaneous packaging.*

8 *(B) Identification of expired or contaminated medications.*

9 *(C) The product characteristics that need to be checked for*  
10 *each drug dispensed from the pharmacy.*

11 *(D) Special packaging or handling requirements, including*  
12 *refrigeration for certain medications.*

13 *(E) Generic names for common name-brand medications.*

14 *(F) Recognition and identification of various dosage forms.*

15 *(G) Common medical abbreviations and symbols used in*  
16 *pharmacy.*

17 *(H) Basic mathematical principles used in pharmacy*  
18 *calculations, including conversions between and within metric,*  
19 *avoirdupois, and apothecary systems.*

20 *(2) The practical component of the training shall consist of at*  
21 *least two hours of supervised practice in which the trainee both*  
22 *observes proper checking procedures and performs proper*  
23 *checking procedures under the direct observation of the*  
24 *supervisor.*

25 *(c) The board may, by regulation, establish other rules for*  
26 *hospitals utilizing specially trained pharmacy technicians*  
27 *pursuant to this section.*

28 *(d) The board may order a hospital to cease activities*  
29 *authorized by this section at any time a hospital fails to satisfy*  
30 *the board that it is capable of continuing to meet the*  
31 *requirements of this section.*

32 *(e) Data and records required by this section shall be retained*  
33 *in each participating hospital for at least three years.*

34 *(f) Medication that has been placed in floor or ward stock or*  
35 *unit dose distribution systems pursuant to this section shall not*  
36 *be administered to a patient except by a licensed health care*  
37 *provider practicing within the scope of his or her license.*

38 *(g) Legal responsibility or liability for errors or omissions that*  
39 *occur as a result of a pharmacy technician checking another*  
40 *pharmacy technician's work pursuant to this section shall be*



1 *limited to the holder of the pharmacy permit and the pharmacist*  
2 *in charge.*

3 *4128.1. (a) Every hospital utilizing pharmacy technicians to*  
4 *check the work of other pharmacy technicians pursuant to*  
5 *Section 4128 shall maintain for inspection by the board a current*  
6 *list of all pharmacy technicians that have been qualified to*  
7 *perform checking functions.*

8 *(b) A pharmacy technician is not eligible to be qualified*  
9 *pursuant to this article unless he or she:*

10 *(1) Is currently certified by the Pharmacy Technician*  
11 *Certification Board.*

12 *(2) Is currently registered with the board as a pharmacy*  
13 *technician pursuant to Section 4202.*

14 ~~SEC. 2.~~

15 *SEC. 3.* No reimbursement is required by this act pursuant to  
16 Section 6 of Article XIII B of the California Constitution because  
17 the only costs that may be incurred by a local agency or school  
18 district will be incurred because this act creates a new crime or  
19 infraction, eliminates a crime or infraction, or changes the  
20 penalty for a crime or infraction, within the meaning of Section  
21 17556 of the Government Code, or changes the definition of a  
22 crime within the meaning of Section 6 of Article XIII B of the  
23 California Constitution.



# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: SB 592**

**VERSION: AMENDED MARCH 29, 2005**

**AUTHOR: AANESTEAD**

**SPONSOR: CALIFORNIA SOCIETY OF  
HEALTH SYSTEMS PHARMACISTS**

**RECOMMENDED POSITION: SUPPORT**

**SUBJECT: TECHNICIAN CHECKING TECHNICIAN**

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### **Existing Law:**

- 1) Requires pharmacy technicians to be licensed by the board. (B&P 4115)
- 2) Permits pharmacy technicians to perform packaging, manipulative, repetitive, or other nondiscretionary tasks under the direct supervision of a pharmacist as follows:
  - a. Removing drugs from stock.
  - b. Counting, pouring, or mixing pharmaceuticals
  - c. Placing product in a container.
  - d. Affixing a label or labels to the container.
  - e. Packaging and repackaging.(CCR 1793.2)
- 3) Requires pharmacy technicians to possess a high school education and fulfill one of the following requirements to be licensed:
  - a. Associate degree in pharmacy technology.
  - b. Complete a training course approved by the board.
  - c. Is eligible to take the board examination for licensure as a pharmacist.(CCR 1793.5, 1793.6)

### **This Bill:**

- 1) Permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. (B&P 4128 Added)
- 2) Requires hospitals implementing TCT to do the following:
  - a. Conduct ongoing training for technicians.
  - b. Conduct continuous quality improvement programs to audit the performance of technicians in TCT programs.
  - c. Remove any technician in TCT programs whose accuracy rate falls below 99.8 percent.

- d. Possess a current accreditation from the Joint Commission on the Accreditation of Health Care Organizations (JCAHO), or another nationally recognized accrediting organization.
- e. Be inspected by the Board of Pharmacy.
- f. Establish a program using pharmacists to provide clinical services.

(B&P 4128 Added)

3) Requires training for pharmacy technicians to include both didactic and practical elements, and to be completed prior to technicians commencing participation in the checking program.

- a. The didactic component of the training shall consist of at least four hours of education covering the following topics:
  - i. Information required to be on the label of unit dose or extemporaneous packaging.
  - ii. Identification of expired or contaminated medications.
  - iii. The product characteristics that need to be checked for each drug dispensed from the pharmacy.
  - iv. Special packaging or handling requirements, including refrigeration for certain medications.
  - v. Generic names for common name-brand medications.
  - vi. Recognition and identification of various dosage forms.
  - vii. Common medical abbreviations and symbols used in pharmacy.
  - viii. Basic mathematical principles used in pharmacy calculations, including conversions between and within metric, avoirdupois, and apothecary systems.

- b. The practical component of the training shall consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures and performs proper checking procedures under the direct observation of the supervisor.

(B&P 4128 Added)

4) Permits the board to adopt other rules related to TCT.

(B&P 4128 Added)

5) Permits the board to order a hospital to cease a TCT program.

(B&P 4128 Added)

6) Requires that data and records for TCT programs be retained for three years.

(B&P 4128 Added)

7) Specifies that legal responsibility for errors in the TCT process is that of the pharmacy and the pharmacist-in-charge.

(B&P 4128 Added)

8) Requires hospitals to have a list of technicians in TCT programs available for inspection by the board.

(B&P 4128.1 Added)

9) Requires pharmacy technicians participating in TCT programs be certified by the Pharmacy Technician Certification Board.

(B&P 4128.1 Added)

### **Comment:**

**1) Author's Intent.** The author is seeking to apply the model TCT program evaluated in a study project at Cedars Sinai Medical Center and Long Beach Memorial Hospital. The results of that study were published in the American Journal of Health System Pharmacy, June 2002, and found the practice to be safe and that TCT allowed staff pharmacists to spend more time addressing clinical issues with patients and prescribers.

**2) Legislative History.** In 2003 the author introduced SB 393, a bill similar to SB 592. SB 393 was opposed by the United Food and Commercial Union (labor), consequently the measure failed to make it beyond its second committee hearing.

The sponsor of SB 592 is engaging labor in discussions in hopes labor will either support or remain neutral on the bill.

**3) Board History.** At its October 2001 meeting, the board voted to support legislation that would allow a pharmacy technician to check another pharmacy technician filling unit-dose cassettes in an inpatient hospital pharmacy. At that meeting the board expressed a desire for TCT programs to emulate those operated by Cedars-Sinai and Long Beach Memorial under the board waiver.

In April 2003, the board voted to support SB 393.

At the January 2004 board meeting the board approved a two-year pilot program at UCSF / Cedars to allow TCT to continue while documentation of duties preformed by pharmacists continue. This pilot program will end in 2006.

**4) Amended on March 29, 2005.** The amendments 1) detail training for pharmacy technicians who participate in the program, and 2) specified requirements for the quality improvement program required by the measurer. This version of the bill is similar to AB 393, as amended on July 16, 2003.

## **5) History.**

2005

June 14	Set, first hearing. Failed passage in committee. Reconsideration granted.
May 26	To Com. on HEALTH.
May 9	In Assembly. Read first time. Held at Desk.
May 9	Read third time. Passed. (Ayes 23. Noes 8. Page 972.) To Assembly.
May 3	Read second time. To third reading.
May 2	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
Apr. 21	Set for hearing May 2.
Apr. 18	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 4. Noes 1. Page 625.) Re-referred to Com. on APPR.
Mar. 30	Set for hearing April 18.
Mar. 29	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 3	To Com. on B., P. & E.D.
Feb. 19	From print. May be acted upon on or after March 21.
Feb. 18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE JUNE 23, 2005  
AMENDED IN ASSEMBLY MAY 26, 2005  
AMENDED IN ASSEMBLY APRIL 18, 2005  
AMENDED IN ASSEMBLY APRIL 7, 2005  
AMENDED IN ASSEMBLY FEBRUARY 11, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

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**ASSEMBLY BILL****No. 71**

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**Introduced by Assembly Members Chan and Frommer  
(Coauthors: Assembly Members Bass, Cohn, Evans, Gordon,  
Koretz, and Pavley)**

January 3, 2005

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An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 71, as amended, Chan. Pharmaceuticals: adverse drug reactions: Office of California Drug Safety Watch.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would establish the Office of California Drug Safety Watch within the department and would require the office, among other duties, to establish a central repository of information about the safety and effectiveness of prescription drugs ~~frequently advertised on television~~, *that belong to classes of drugs for which there have been*

*recently published reports of safety concerns, that have been frequently advertised directly to consumers, and for which there are recently published systematically reviewed evidence-based research that includes research on side effects and safety issues. The bill would require the office to disseminate information to health care professionals and consumers through an Internet Web site; and to request assistance from the University of California and California State University, and to rely on systematically reviewed evidence-based research.*

*This bill would require the department to impose a fee on any manufacturer of drugs sold in the state, in an amount based on the drug manufacturer's market share of the total amount of drugs sold in the state.*

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) Since 1997, when the United States Food and Drug
- 4 Administration (FDA) allowed drug manufacturers to advertise
- 5 directly to consumers, the amount spent on advertising has risen
- 6 dramatically.
- 7 (b) According to the United States General Accounting Office
- 8 (GAO) report, the pharmaceutical industry spent \$2.7 billion in
- 9 2001 on direct-to-consumer advertising. A December 6, 2004,
- 10 New York Times report states that such spending has reached
- 11 \$3.8 billion.
- 12 (c) According to the same GAO report, while overall spending
- 13 on drug promotion was less than spending on research and
- 14 development (\$19.1 billion versus \$30.3 billion), spending on
- 15 direct-to-consumer advertising is increasing at a faster rate than
- 16 overall drug promotion spending or spending on research and
- 17 development. Between 1997 and 2001, the increase in
- 18 direct-to-consumer advertising was 145 percent compared to a 59
- 19 percent increase for research and development.
- 20 (d) Although the FDA is responsible for postmarket
- 21 surveillance of prescription drugs, numerous concerns have been
- 22 raised about the adequacy of these efforts.

1 (e) An unpublished internal FDA study from 2002 revealed  
2 that 18 percent of FDA scientists reported being pressured to  
3 approve a new drug “despite reservations about the safety,  
4 efficacy or quality of the drug.”

5 (f) A 1999 FDA survey and a Kaiser Family Foundation  
6 survey both found that more than 50 million people respond to  
7 drug advertisements by asking their doctor whether the  
8 advertised medications might work for them. At the same time,  
9 both surveys showed that almost 60 percent of consumers found  
10 the side-effect warnings in these advertisements to be inadequate.

11 (g) Pressure to get new drugs to market, combined with the  
12 vast amount of drug marketing undertaken by manufacturers,  
13 make it difficult to address a threat once it is identified. Recent  
14 studies linking the use of popular, widely promoted prescription  
15 drugs to serious public health concerns point to the need for  
16 greater oversight to protect the public.

17 *(h) Drugs that are frequently advertised to consumers present*  
18 *special safety concerns because direct-to-consumer advertising*  
19 *is likely to minimize potential side effects and safety concerns*  
20 *and because advertised drugs are likely to be highly utilized by*  
21 *Californians.*

22 ~~(h)~~

23 (i) Californians do not have a reliable central repository of  
24 information about prescription drug safety and effectiveness.

25 ~~(i)~~

26 (j) California physicians and other prescribers could benefit  
27 from a reliable central repository of information about  
28 prescription drug safety and effectiveness.

29 ~~(j)~~

30 (k) Various nationally respected sources of clinical  
31 information are available as sources for a central repository of  
32 information about prescription drug safety and effectiveness.

33 ~~(k)~~

34 (l) Safer and more effective prescription drugs within a class  
35 may also be among the less expensive prescription drugs within  
36 that class, meaning that a reliable central repository of  
37 information about prescription drug safety and effectiveness  
38 would create opportunities for prescription drug cost savings.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Office of California Drug Safety Watch

111657. (a) There is hereby established in the State Department of Health Services the Office of California Drug Safety Watch, which shall do all of the following, to provide Californians with information on the safety and effectiveness of prescription drugs:

(1) Establish a central repository of information about the safety and effectiveness of prescription drugs that are frequently advertised on television, selected pursuant to subdivision (b). The repository shall not include information about any therapeutic class of drugs that is used primarily to treat mental illness.

(2) Disseminate information to California health care professionals and consumers through an Internet Web site that shall include links to other relevant Web-based information that has been professionally reviewed and approved. *The Internet Web site shall include the following statement: "Many factors enter into selecting the proper drug for individual patients. Before changing any medication, a patient shall consult with his or her treating physician or other prescriber."*

(3) Ensure that the dissemination of information is done in a culturally competent manner and addresses the differential impact of medications within a class based on gender, age, and ethnicity, when that information is available. *When there is no evidence supporting the differential impact of medication among various demographic groups, it shall be noted on the Internet Web site.*

~~(4) In selecting therapeutic classes of drugs about which to develop information, the office shall choose the four most frequently advertised classes of drugs for which there is recently published systemically reviewed evidence-based research.~~

~~(5) Request appropriate units of the University of California and the California State University to provide assistance.~~

~~(6) Rely on systematically reviewed evidence-based research.~~

~~(b) The office shall coordinate its activities with other state departments and agencies to avoid unnecessary duplication.~~



1     ***(b) In selecting therapeutic drugs about which to develop***  
2     ***information, the office shall only include classes of drugs that***  
3     ***have all of the following characteristics:***

4     ***(1) Classes of drugs for which there have been recently***  
5     ***published reports of safety concerns.***

6     ***(2) Classes of drugs that have been frequently advertised***  
7     ***directly to consumers.***

8     ***(3) Classes of drugs for which there are recently published***  
9     ***systemically reviewed evidence-based research that includes***  
10    ***research on side effects and safety issues.***

11    ***(c) The office shall request the appropriate units of the***  
12    ***University of California and the California State University to***  
13    ***provide assistance in implementing this article.***

14    ***(d) The office shall coordinate its activities with other state***  
15    ***departments and agencies to avoid unnecessary duplication.***

16    ***(e) The office shall rely on systemically reviewed***  
17    ***evidence-based research.***

18    ***(f) The process that the office uses to identify relevant***  
19    ***research and standards of clinical evidence shall be transparent***  
20    ***and publicly available.***

21    111657.1. For purposes of this article, the following terms  
22    have the following meanings:

23    ~~(a) “Evidence-based research” means prescription drug~~  
24    ~~research in which the drugs in question have been administered~~  
25    ~~to experimental and control groups and the subsequent effect of~~  
26    ~~the drugs has been observed through those groups.~~

27    ***(a) “Evidence-based research” means research that is based***  
28    ***on clinical evidence, including therapeutic outcomes, and that***  
29    ***uses a hierarchy of evidence to evaluate the reliability of the***  
30    ***research. In well-conducted research, the hierarchy of evidence,***  
31    ***from highest to lowest, is the system review of randomized***  
32    ***clinical trials, individual randomized clinical trials, controlled***  
33    ***trials, cohort studies, and case control studies.***

34    ***(b) “Systematically reviewed” means review of***  
35    ***evidence-based research that uses rigorous, unbiased methods to***  
36    ***examine the similarities and differences of results across many***  
37    ***individual research studies. The goal of a systematic review is to***  
38    ***estimate the comparative effectiveness and safety of health care***  
39    ***treatments. A systematic approach to reviewing the evidence***

1 increases the reliability of the results, and the transparency of the  
2 procedures.

3 ~~(e) “Most frequently advertised classes of drugs” means the~~  
4 ~~therapeutic classes of drugs most frequently advertised on~~  
5 ~~television for the six-month period prior to the date the office~~  
6 ~~begins compiling the drug safety and effectiveness information~~  
7 ~~required by this article. Frequently advertised classes of drugs~~  
8 ~~shall not include any therapeutic class that is used primarily to~~  
9 ~~treat mental illness.~~

10 *111657.2. (a) There is hereby imposed, pursuant to this*  
11 *section, a fee on manufacturers of drugs sold in the state.*

12 *(b) (1) The specific fee to be assessed on a drug manufacturer*  
13 *shall be established by the State Department of Health Services,*  
14 *to the maximum extent practicable, on the basis of a drug*  
15 *manufacturer’s market share of the total amount of drugs sold in*  
16 *the state.*

17 *(2) A fee shall not be assessed on a drug manufacturer that*  
18 *can demonstrate, as determined by the State Department of*  
19 *Health Services, that it does not manufacture drugs that have the*  
20 *characteristics described in subdivision (b) of Section 111657.*

21 *(c) The fee shall be assessed and collected annually by the*  
22 *State Board of Equalization in accordance with Part 22*  
23 *(commencing with Section 43001) of Division 2 of the Revenue*  
24 *and Taxation Code. The fees collected shall be deposited in the*  
25 *Drug Safety Watch Fund, which is hereby established in the State*  
26 *Treasury. Moneys in the fund shall be expended, upon*  
27 *appropriation by the Legislature, for the purposes of this article,*  
28 *including the costs of the State Board of Equalization for*  
29 *collection and administration of fees. All interest earned on the*  
30 *moneys that have been deposited into the Drug Safety Watch*  
31 *Fund shall be retained in the fund.*

32 *(d) The fees collected pursuant to this section and the earnings*  
33 *therefrom shall be used solely for the purposes of implementing*  
34 *this article. The department shall not collect fees pursuant to this*  
35 *section in excess of the amount reasonably anticipated by the*  
36 *department to fully implement this article. The department shall*  
37 *not spend more than it collects from the fees, and the earnings*  
38 *thereon, in implementing this article.*

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# **CALIFORNIA STATE BOARD OF PHARMACY**

## **BILL ANALYSIS**

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**BILL NUMBER: AB 71**

**VERSION: AMENDED APRIL 18, 2005**

**AUTHOR: CHAN et. al.**

**SPONSOR: CHAN**

**RECOMMENDED POSITION: NO POSITION**

**SUBJECT: PHARMACEUTICALS: ADVERSE DRUG REACTIONS: OFFICE OF CALIFORNIA DRUG SAFETY WATCH**

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### **Existing Law:**

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers about adverse drug reactions.

### **This Bill:**

- 1) Establishes the Office of California Drug Safety Watch (office) within the Department of Health Services (DHS). (H&S 111657 Added)
- 2) Requires the office to do all of the following:
  - a. Establish a central repository of information about the safety and effectiveness of prescription drugs.
  - b. Disseminate information to health care professionals and consumers through an Internet Web site that would include links to other relevant web-based information that has been professionally reviewed and approved.
  - c. Assure that the dissemination of information is done in a culturally competent manner.
  - d. Request units of the University of California and the California State University to provide assistance.
  - e. Rely on systematically reviewed evidence-based research.
  - f. Give priority, when selecting therapeutic classes of drugs about which to develop information, to therapeutic classes that have one or all of the following characteristics:
    - i. Classes of drugs in which there have been recently published reports of safety concerns.
    - ii. Classes of drugs that have been advertised on television directly to consumers.

- iii. Classes of drugs for which there is recently published systematically reviewed evidence-based research.

(H&S 111657 Added)

3) Authorize the office to review the formularies of all state-funded programs for their utilization of systematically reviewed evidence-based research. (H&S 111657 Added)

4) Requires the office to coordinate its activities with other state departments and agencies to avoid unnecessary duplication. (H&S 111657 Added)

5) Defines the following terms:

- a. Evidence-based research to mean prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups.
- b. Systematically reviewed to mean review of evidence-based research that uses rigorous, unbiased methods to examine the similarities and differences of results across many individual research studies. The goal of a systematic review is to estimate the comparative effectiveness and safety of healthcare treatments. A systematic approach to reviewing the evidence increases the reliability of the results, and the transparency of the procedures.

(H&S 111657.1 Added)

### **Comment:**

**1) Author's Intent.** The author is concerned about drug safety and the perceived inability of the Federal government to take action to warn the public about potentially dangerous drugs.

**2) Necessity for Bill?** The intent of this legislation is to provide Californians with a reliable central repository of information about prescription drugs safety and effectiveness. This type of information is currently available through many sources, including the FDA, the Oregon Drug Effectiveness Review Project (ODERP), Consumers Union [Reports], and the AARP; all of which have Web sites that consumers and healthcare professionals can access for information. Given that reliable information is available, perhaps it would better and less costly for the Administration to direct DHS to establish a Web site with links to information on drug safety, rather than passing legislation that would require to DHS to establish a new program that essentially duplicates what is being done by other entities.

**3) Drugmakers Plans for Voluntary Disclosure on the Internet.** Reuters News reported on May 16, 2005 that the pharmaceutical industry plans to launch a global website in September, pooling information on ongoing and completed clinical trials, as it steps up a campaign to reassure patients about medicine safety. Drugmakers in the United States, Europe and Japan agreed in January on a voluntary code to publish detailed clinical trials data and said at the time they were exploring ways to make this information available through a single "window". The new portal will establish links to company websites and other commercial and government-sponsored websites containing information provided by firms. The voluntary code has the backing of major groups, including Pfizer Inc, GlaxoSmithKline Plc, Merck, AstraZeneca Plc, Novartis AG and Sanofi-Aventis SA. The move does not represent full disclosure, however, since early-stage phase I studies on healthy volunteers -- often the first sign a company has a good hunch about a new drug approach -- are exempt and there is no obligation to reveal the results of studies before a drug is approved. Companies also have up to a year to publish results. Drugmakers, already struggling to find enough new medicines to sustain historic growth rates, need to tread a fine line when deciding how much information to disclose about trials, according to industry analysts. While seeking to satisfy legislators, they are anxious to hold back anything that could give them a competitive advantage in an increasingly cut-throat industry.

**4) Amended on April 18, 2005.** The April 18<sup>th</sup> amendment deleted reference to the Oregon Drug Effectiveness Review Project from the legislative findings section of the bill. The OREDP is a three-year, \$4.2 million collaboration of organizations that includes DHS and CalPERS. The project was formed to obtain the best available evidence on effectiveness and safety comparisons between drugs in the same class, and to apply the information to public policy and related activities.

**5) Other Legislation.** Two other bills dealing with drug safety and reporting requirements have been introduced this session.

SB 380 (Alquist) Drugs: Adverse Event Reporting, would require licensed health professionals and a health facilities to report serious adverse drug events that they observe to MedWatch, the FDA's drug safety information and adverse event reporting program. (MedWatch is a voluntary reporting program that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.)

SB 329 (Cedillo) California Prescription Drug Safety and Effectiveness Commission. This is a spot bill and may be amended for other purposes.

**6) Federal Legislation.** On May 4, 2005, Congressman Hinchey (D-NY) introduced H.R. 2090, the Food and Drug Administration Improvement Act of 2005. This bill would: 1) establish within the FDA a Center for Postmarket Drug Safety and Effectiveness to monitor all approved drugs as well as all advertisements and promotions associated with those products; 2) prohibit the FDA from collecting fees paid by companies it regulates and instead, deposit those funds into the general fund of the Treasury; 3) empower the FDA with the authority to mandate that companies conduct post-marketing studies of FDA-approved drugs; and 4) enable the FDA to mandate changes to labels of FDA-approved products if a new risk is discovered. HR 2090 has been referred to the House Committee on Health.

## **7) History.**

2005

April 27 In committee: Set, first hearing. Referred to APPR. suspense file.

Apr. 19 Re-referred to Com. on APPR.

Apr. 18 Read second time and amended.

Apr. 14 From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 9. Noes 4.) (April 12).

Apr. 11 Re-referred to Com. on HEALTH.

Apr. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

Feb. 15 Re-referred to Com. on HEALTH.

Feb. 11 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

Jan. 18 Referred to Com. on HEALTH.

Jan. 4 From printer. May be heard in committee February 3.

Jan. 3 Read first time. To print.

AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 4, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

**ASSEMBLY BILL**

**No. 72**

**Introduced by Assembly Members Frommer and Chan  
(Coauthors: Assembly Members Bass, Evans, Gordon, Koretz,  
Nava, Pavley, and Salinas)**

January 3, 2005

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An act to add Chapter 9 (commencing with Section 119500) to Part 15 of Division 104 of the Health and Safety Code, relating to prescription drug trials.

LEGISLATIVE COUNSEL'S DIGEST

AB 72, as amended, Frommer. Prescription drugs: clinical trials.

Existing law regulates the labeling, sale, and use of prescription drugs and devices.

This bill would establish the Patient Safety and Drug Review Transparency Act in order to ~~assure~~ *ensure* that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. The bill would prohibit an institutional review board with responsibility for ensuring the protection of the rights, safety, and well-being of human subjects involved in clinical trials of prescription drugs from approving any clinical trial related to a prescription drug unless the sponsor certifies in writing that it (1) will register the clinical trial, no later than 21 days after ~~it begins~~ *it begins its approval by the institutional review board*, with a government sponsored and public clinical trial registry, (2) will publish the results of the study, and (3) has complied with the registry and publication

requirements for any prior ~~study~~ *clinical trial* that was approved by the board.

~~This bill would prohibit the board from approving any study related to a prescription drug if the sponsor failed during a prior study that was approved by the board to comply with the above requirements. Prior to approval, the bill would require the board to review whether the sponsor, in prior approved studies, actually complied with those requirements.~~

The bill would provide that any sponsor who does not comply with the requirements it certified in writing is liable for a civil penalty of \$1,000 per violation. The bill would authorize the Attorney General, a district attorney, or city attorney to bring an action against a sponsor to ~~recover civil penalties~~ *enforce compliance with its requirements*.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. Chapter 9 (commencing with Section 119500)  
2 is added to Part 15 of Division 104 of the Health and Safety  
3 Code, to read:

4  
5 CHAPTER 9. ~~INFORMATION REQUIRED FOR DRUG STUDIES~~  
6 *PATIENT SAFETY AND DRUG REVIEW TRANSPARENCY*  
7

8 119500. (a) This chapter may be referred to as the “Patient  
9 Safety and Drug Review Transparency Act.”

10 (b) The purpose of this act is to ~~assure~~ *ensure* that information  
11 regarding clinical trials of prescription drugs is available to the  
12 public, physicians, and researchers. Making information about  
13 drug trials and their results available in a national, publicly  
14 accessible database will improve the safety of human subjects  
15 and provide all citizens of this state with complete safety  
16 information about the prescription drugs they take.

17 (c) For purposes of this chapter, the following terms have the  
18 following meanings:

19 (1) “Clinical trial” means a *Phase 2, 3, or 4* clinical  
20 investigation as defined by the federal Food and Drug  
21 Administration ~~that involves any experiment~~ to test the safety or  
22 efficacy of a drug or biological product with one or more human

1 subjects and is intended to be submitted to, or held for inspection  
2 by, the federal Food and Drug Administration as part of an  
3 application for a research or marketing permit.

4 (2) "Clinical trial registry" means a publicly available  
5 ~~databank~~ database established by the National Library of  
6 Medicine pursuant to 42 U.S.C. Section 282 (j).

7 (3) "Institutional review board" means an independent body  
8 constituted of medical, scientific, and nonscientific members,  
9 whose responsibility is to ensure the protection of the rights,  
10 safety, and well-being of human subjects involved in clinical  
11 trials of prescription drugs by, among other things, reviewing,  
12 approving, and providing continuing review of trial protocol and  
13 the methods and material to be used in obtaining and  
14 documenting informed consent of the trial subjects. *The*  
15 *institutional review board is constituted under Subtitle A*  
16 *(commencing with Section 46.101) of Part 46 of Title 45 of the*  
17 *Code of Federal Regulations, to review and monitor research*  
18 *involving human subjects.*

19 (4) "Sponsor" means the manufacturer, or if the manufacturer  
20 provides no monetary support for the trial, the person who  
21 provides the majority of monetary support, or, where the majority  
22 funder is a state or federal agency, the principal investigator.

23 ~~(d) An institutional review board shall not approve any clinical~~  
24 ~~trial related to a prescription drug unless the sponsor certifies in~~  
25 ~~writing that it has done or will do all of the following:~~

26 *(d) A sponsor of a clinical investigation shall certify to the*  
27 *relevant institutional review board and to the Attorney General*  
28 *that the sponsor has done or will do all of the following:*

29 (1) Register the clinical trial, no later than 21 days after it  
30 ~~begins, by providing information necessary for publication in a~~  
31 ~~government-sponsored approval of the clinical trial by the~~  
32 ~~institutional review board, by providing information necessary~~  
33 ~~for publication in a government-sponsored~~ and public clinical  
34 trial registry in the manner required by regulations or other  
35 guidance established by the National Library of Medicine or the  
36 United States Secretary of Health and Human Services.

37 (2) Publish the results of the study by providing the results of  
38 ~~the study for publication~~ *summary results of the trial, whether*  
39 *positive or negative,* in a government sponsored and public  
40 clinical trial registry, in a manner required by regulations or other



1 guidance established by the National Library of Medicine or the  
2 United States Secretary of Health and Human Services, *in a*  
3 *peer-reviewed medical journal*, or in another publicly accessible  
4 database.

5 (3) Complied with the provisions of paragraphs (1) and (2) for  
6 any prior ~~study~~ *clinical trial* that was approved by the board  
7 pursuant to this chapter.

8 ~~(e) An institutional review board shall not approve any study~~  
9 ~~related to a prescription drug if the sponsor failed during a prior~~  
10 ~~study that was approved by the board pursuant to this chapter to~~  
11 ~~comply with the requirements it certified in writing under~~  
12 ~~subdivision (d). Prior to approval, the board shall review whether~~  
13 ~~the sponsor, in prior studies approved pursuant to this chapter,~~  
14 ~~actually complied with those requirements.~~

15 ~~(f) Any sponsor who does not comply with the requirements it~~  
16 ~~certified in writing under subdivision (d) shall be liable for a civil~~  
17 ~~penalty of one thousand dollars (\$1,000) per violation payable to~~  
18 ~~the general fund of the entity bringing the action. Each day a~~  
19 ~~sponsor is in violation shall be considered a separate violation.~~  
20 ~~The Attorney General, a district attorney, or city attorney may~~  
21 ~~bring an action against a sponsor to recover civil penalties for not~~  
22 ~~complying with the requirements the sponsor certified in writing~~  
23 ~~under subdivision (d).~~

24 *(e) Any sponsor who does not comply with the requirements of*  
25 *this chapter within 30 days after receipt of written notice from*  
26 *the Attorney General, a district attorney, or a city attorney shall*  
27 *be liable for a civil penalty of one thousand dollars (\$1,000) per*  
28 *violation payable to the general fund of the entity bringing the*  
29 *action. Each day a sponsor remains in violation of this chapter*  
30 *after the conclusion of the 30-day period shall be considered a*  
31 *separate violation. The Attorney General, a district attorney, or*  
32 *a city attorney may bring an action against a sponsor to enforce*  
33 *compliance with the requirements of this chapter.*



# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: AB 72**

**VERSION: AMENDED MAY 26, 2005**

**AUTHOR: FROMMER et. al.**

**SPONSOR: FROMMER**

**RECOMMENDED POSITION: NO POSITION**

**SUBJECT: CLINICAL TRIALS**

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### **Existing Law:**

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establishes the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers to report adverse drug reactions.

### **This Bill:**

- 1) Establishes the Patient Safety and Drug Review Transparency Act.
- 2) Defines the terms: "Clinical trial", "Clinical trial registry", "Institutional review board", and "Sponsor."
- 3) Requires a sponsor of a clinical investigation to certify to the relevant institutional review board and to the Attorney General that the sponsor has done or will do all of the following:
  - a. Register the clinical trial, no later than 21 days after approval of the clinical trial by the institutional review board, by providing information necessary for publication in a government-sponsored and public clinical trial registry in the manner required by regulations or other guidance established by the National Library of Medicine or the United States Secretary of Health and Human Services.
  - b. Publish the summary results of the trial, whether positive or negative, in a government sponsored and public clinical trial registry, or other publicly accessible database.
  - c. Complied with the provisions of the measure for any prior clinical trial that was approved by the board.
- 5) Establishes a civil penalty of \$1,000 per violation for any sponsor who does not comply with provisions of the bill. Each day a sponsor is in violation would be considered a separate violation.

(H&S 119500 Added)

### **Comment:**

**1) Author's Intent.** The author's intent is to assure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers.

## 2) History.

2005

- June 2      Action rescinded and record expunged whereby the bill was read third time and whereby a final roll call vote was taken. To inactive file on motion of Assembly Member Frommer
- May 27      Read second time. To third reading.
- May 26      From committee: Amend, and do pass as amended. (Ayes 11. Noes 5.) (May 25).  
Read second time and amended. Ordered returned to second reading.
- May 11      In committee: Set, first hearing. Referred to APPR. suspense file.
- Apr. 13      From committee: Do pass, and re-refer to Com. on APPR.  
Re-referred. (Ayes 10. Noes 3.) (April 12).
- Apr. 5      Re-referred to Com. on HEALTH.
- Apr. 4      From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
- Jan. 18      Referred to Coms. on HEALTH and JUD.
- Jan. 4      From printer. May be heard in committee February 3.
- Jan. 3      Read first time. To print.

AMENDED IN SENATE JUNE 23, 2005  
AMENDED IN ASSEMBLY APRIL 20, 2005  
AMENDED IN ASSEMBLY APRIL 6, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

**ASSEMBLY BILL**

**No. 74**

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**Introduced by Assembly Members Gordon and Frommer**  
**(Coauthors: Assembly Members Chan, Chavez, Koretz, Laird,**  
**Matthews, Pavley, Ridley-Thomas, and Ruskin)**  
(Coauthor: Senator Alquist)

January 3, 2005

---

An act to add Article 5 (commencing with Section 110243) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 74, as amended, Gordon. California R Prescription Drug Hotline.

Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

This bill would require the department to establish the California R Prescription Drug Hotline, on or before July 1, 2006, to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices. The bill would establish a maximum cost per call to the hotline and require the hotline to provide specific information.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. The Legislature finds and declares all of the  
2 following:

3 (a) Prescription drugs have become essential for ensuring the  
4 health of millions of Californians.

5 (b) Increased spending on prescription drugs is a significant  
6 driver of increases in overall health care costs.

7 (c) Rising out-of-pocket costs for prescription drugs are  
8 placing a growing burden on California consumers, as federal  
9 government statistics show that in 2002 the increase in  
10 consumers' out-of-pocket costs for prescription drugs was greater  
11 than the increase in out-of-pocket costs for all other health care  
12 expenditures.

13 (d) The price of brand name drugs is rising faster than the rate  
14 of inflation, with a recent study showing that the price of 30  
15 drugs most frequently used by the elderly rose by over four times  
16 the rate of inflation in 2003 and that some drugs increased in  
17 price by 10 times the rate of inflation in that period.

18 (e) The rising cost of prescription drugs jeopardizes the health  
19 of seniors, the disabled, and other consumers who cannot afford  
20 the medication they need to stay healthy.

21 (f) California residents face a growing need for assistance in  
22 finding information about sources for prescription drugs at  
23 affordable prices.

24 SEC. 2. Article 5 (commencing with Section 110243) is  
25 added to Chapter 2 of Part 5 of Division 104 of the Health and  
26 Safety Code, to read:

27

28 Article 5. California Rx Prescription Drug Hotline

29

30 110243. (a) The State Department of Health Services shall  
31 establish the California Rx Prescription Drug Hotline to provide  
32 information to consumers and health care providers about options  
33 for obtaining prescription drugs at affordable prices.

34 (b) The department shall establish a low-cost 1-900 telephone  
35 number on or before July 1, 2006. Callers shall be provided with

1 information about options for obtaining prescription drugs at  
2 affordable prices. The cost per call to the hotline shall not exceed  
3 50 cents (\$0.50) and the hotline shall, at a minimum, provide  
4 information about all of the following:

5 ~~(1) Prescription drug benefits available to Medicare~~  
6 ~~beneficiaries, including the Voluntary Prescription Drug Benefit~~  
7 ~~Program and the Medicare Prescription Drug Discount and~~  
8 ~~Transitional Assistance Program.~~

9 ~~(2)~~

10 (1) State programs that provide drugs at discounted prices for  
11 California residents.

12 ~~(3)~~

13 (2) Federal programs that provide drugs at discounted prices  
14 for United States residents.

15 ~~(4)~~

16 (3) Pharmaceutical manufacturer patient assistance programs  
17 that provide free or low-cost prescription drugs to qualifying  
18 individuals.

19 ~~(5)~~

20 (4) Other informational resources as deemed appropriate by  
21 the department that help California residents to safely obtain  
22 prescription drugs at affordable prices, including, but not limited  
23 to, both of the following:

24 (A) Information regarding the availability of prescription  
25 drugs from Canada that are distributed from pharmacies licensed  
26 in that country and that meet standards and regulations prescribed  
27 by the state or federal government.

28 (B) Telephone numbers and *Internet* Web sites of health plans  
29 and health insurers regarding their prescription drug formularies.

30 ~~(6)~~

31 (5) Price comparisons of at least 50 commonly prescribed  
32 brand name prescription drugs, including typical prices charged  
33 by all of the following:

34 (A) Licensed pharmacies in the state.

35 (B) Licensed pharmacies in other states.

36 (C) Pharmacies located in Canada that are licensed by that  
37 country and that meet standards prescribed by the state and  
38 federal government.

39 (c) The department shall ensure that the hotline established  
40 pursuant to this section is coordinated with and does not

- 1 duplicate other state-funded programs and services, including,
- 2 but not limited to, programs such as the Health Insurance
- 3 Counseling and Advocacy Program (HICAP) established
- 4 pursuant to Chapter 7.5 (commencing with Section 9540) of
- 5 Division 8.5 of the Welfare and Institutions Code, that provide
- 6 information about prescription drug options and costs.
- 7 (d) Any information provided via the hotline shall first be
- 8 approved by professional staff of the department.



# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: AB 74**

**VERSION: AMENDED June 23, 2005**

**AUTHOR: GORDON**

**SPONSOR: GORDON**

**RECOMMENDED POSITION:**

**SUBJECT: CALIFORNIA RX PRESCRIPTION DRUG HOTLINE**

---

### **Existing Law:**

The Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the California Department of Health Services (DHS). (H&S 109875)

### **This Bill:**

- 1) Requires the DHS to establish the California Rx Prescription Drug Hotline (hotline) to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.
- 2) Requires DHS to establish a low-cost 1-900 telephone number on or before July 1, 2006 and to limit the cost per call to the hotline to no more than 50 cents per call. The hotline would provide the following information:
  - a. State programs that provide drugs at discounted prices for California residents.
  - b. Federal programs that provide drugs at discounted prices for United States residents.
  - c. Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.
  - d. Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government.
  - e. Telephone numbers and Web sites of health plans and health insurers regarding their prescription drug formularies.
  - f. Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by 1) licensed pharmacies in the state, 2) licensed pharmacies in other states, and 3) pharmacies located in Canada that are licensed by that country and that meet standards prescribed by the state and federal government.
- 3) Requires that DHS ensure that the hotline is coordinated with and does not duplicate other state-funded programs and services, including, but not limited to, the Health Insurance Counseling and Advocacy Program (HICAP), that provide information about prescription drug options and costs.

(H&S 1010243 Added)



## **Comment:**

**1) Author's Intent.** The author's intent is to provide a one-stop-shop for information on how to obtain low priced prescription drugs. While much of this information is available on the Internet, the author is concerned that it's not getting to senior citizens, many of which who have never used a computer, let alone Internet.

As introduced, the measure would require DHS to establish a 1-900 telephone number for the program. The author is considering amending the bill to link the new program to an existing program and established 1-800 number. One option would be to link the program to the Health Insurance Counseling and Advocacy Program (HICAP), within California Department of Aging. HICAP assists individuals and families with Medicare problems and provides information on Medicare, Medicare supplement insurance, managed care, long-term care planning and health insurance.

**2) Oversight.** One of the many roles a pharmacist fills is acting as a second check for prescribers to insure that the medication a patient has been prescribed is the right medication for the patient's health condition, and that multiple medications will not adversely interact with each other to negatively effect a patient's health. As patients see specialist doctors for multiple health problems, the pharmacist's oversight role become increasingly more important, as any one doctor may not be aware of all the prescription drugs a patient is taking. Additionally, as patients seek lower cost drugs from more than one source (mail order, Internet, or local pharmacy), they will loose the benefit of one pharmacy or pharmacist knowing all the medications a patient is taking and ensuring that the medications will not result in harm to the patient. AB 74 and other bills that direct patients to multiple sources to obtain low cost drugs, may have the unintended result of putting peoples health at risk.

**3) Drug Pricing.** This bill requires DHS to provide price comparisons of commonly prescribed brand name prescription drugs, including typical prices charged by instate pharmacies, pharmacies in other states, and pharmacies in Canada. The problem with this requirement is it is impossible to come up with a "typical price charged" for a given drug. The true cost of a drug is influenced by factors including, but not limited to: discounts, rebates, and reimbursement formulas available to a particular purchaser, the number of manufacturers producing a given drug, and the supply and demand for a given drug in a given geographical area. In an effort to establish a benchmark for prescription drugs, standardized terms have been developed, however each term is limited in its ability to accurately establish the true price of prescription drugs. These terms include: average manufacturer price, average sales price, average wholesale price, federal supply schedule, and wholesale acquisition cost.

**4) Substantive Amendments since the April 27<sup>th</sup> Board Meeting.** Deletion of the provision that would require the hotline to provide information on prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program and the Medicare Prescription Drug Discount and Transitional Assistance Program.

## **6) History.**

2005

June 30 Assembly Rule 47.1 invoked. (Frommer)

June 29 In committee: Set, first hearing. Hearing canceled at the request of author.

June 23 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.

June 15 Referred to Com. on HEALTH.

June 6 In Senate. Read first time. To Com. on RLS. for assignment.

June 2 Read third time, passed, and to Senate. (Ayes 47. Noes 31. Page 2104.)

May 27 Read second time. To third reading.

May 26 From committee: Do pass. (Ayes 12. Noes 5.) (May 25).

May 4 In committee: Set, first hearing. Referred to APPR. suspense file.

Apr. 27 From committee: Do pass, and re-refer to Com. on APPR.Re-referred. (Ayes 7.  
Noes 1.) (April 26).

Apr. 21 Re-referred to Com. on B. & P.

Apr. 20 From committee chair, with author's amendments: Amend, and re-refer to Com.  
on B. & P. Read second time and amended.

Apr. 13 From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes  
10. Noes 4.) (April 12).

Apr. 7 Re-referred to Com. on HEALTH.

Apr. 6 From committee chair, with author's amendments: Amend, and re-refer to Com.  
on HEALTH. Read second time and amended.

Jan. 18 Referred to Coms. on HEALTH and B. & P.

Jan. 4 From printer. May be heard in committee February 3.

Jan. 3 Read first time. To print.

AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY MAY 2, 2005

AMENDED IN ASSEMBLY APRIL 19, 2005

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

## **ASSEMBLY BILL**

**No. 75**

**Introduced by Assembly Members Frommer and Chan**

**(Principal coauthor: Assembly Member Baca)**

**(Coauthors: Assembly Members Bass, Berg, Cohn, Coto,  
De La Torre, Evans, Goldberg, Gordon, Hancock, Klehs,  
Koretz, Leno, Levine, Lieber, Nava, Pavley, Ridley-Thomas,  
Ruskin, Saldana, and Salinas Salinas, and Torrico)**

**(Coauthor: Senator Alquist)**

January 3, 2005

---

An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to prescription drugs.

### LEGISLATIVE COUNSEL'S DIGEST

AB 75, as amended, Frommer. Pharmaceutical assistance program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Rx Plus State Pharmacy Assistance Program, to be administered by the department. The bill would authorize the department to negotiate drug rebate agreements

with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under the program. The bill would establish eligibility criteria and application procedures for California residents to participate in the program. The bill would make it a misdemeanor for a person to intentionally make false declarations as to his or her eligibility or eligibility on behalf of any other person seeking eligibility. Because this bill would create a new crime, it would impose a state-mandated local program.

The bill would establish the California Rx Plus Program Fund, into which all payments received under the program would be deposited, with this fund to be used for the purpose of implementing the program, upon appropriation by the Legislature.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Division 112 (commencing with Section  
2 130500) is added to the Health and Safety Code, to read:

3

4 DIVISION 112. CALIFORNIA RX PLUS STATE  
5 PHARMACY ASSISTANCE PROGRAM

6

7 CHAPTER 1. GENERAL PROVISIONS

8

9 130500. (a) This division shall be known, and may be cited,  
10 as the California Rx Plus State Pharmacy Assistance Program.

11 (b) For purposes of this division, the following definitions  
12 apply:

13 (1) "Department" means the State Department of Health  
14 Services.

15 (2) "Fund" means the California Rx Plus Program Fund.

1 (3) "Manufacturer" means a drug manufacturer, as defined in  
2 Section 4033 of the Business and Professions Code.

3 (4) "Program" means the California Rx Plus State Pharmacy  
4 Assistance Program.

5 (5) (A) "Qualified resident" means a resident of California  
6 who has a *gross* family income equal to or less than 400 percent  
7 of the federal poverty guidelines, as updated periodically in the  
8 Federal Register by the United States Department of Health and  
9 Human Services under the authority of Section 673(2) of the  
10 Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec.  
11 9902(2)).

12 (B) "Qualified resident" also means a resident of the state  
13 whose family incurs unreimbursed expenses for prescription  
14 drugs that equal 5 percent or more of *gross* family income or  
15 whose total unreimbursed medical expenses equal 15 percent or  
16 more of *gross* family income.

17 (C) For purposes of this paragraph, the cost of drugs provided  
18 under this division is considered an expense incurred by the  
19 family for eligibility determination purposes.

20 (6) "Resident" means a resident of California pursuant to  
21 Section 17014 of the Revenue and Taxation Code.

22 130501. There is hereby established in the State Department  
23 of Health Services, the California Rx Plus State Pharmacy  
24 Assistance Program.

25  
26 CHAPTER 2. ELIGIBILITY AND APPLICATION PROCEDURES  
27

28 130505. (a) To be eligible for the program, a person shall be  
29 a qualified resident, as defined in paragraph (4) of subdivision (b)  
30 of Section 130500 and shall not have outpatient prescription drug  
31 coverage paid for in whole or in part by the Medi-Cal program or  
32 the Healthy Families Program, or any other program that uses  
33 federal funds to pay part or all of the cost of the person's  
34 outpatient prescription drugs.

35 (b) Notwithstanding subdivision (a), a person enrolled in  
36 Medicare may participate in the program to the extent allowed by  
37 federal law for prescription drugs not covered by Medicare.

38 130506. (a) The department shall establish application forms  
39 and procedures for enrollment in the program. The application  
40 form shall include a requirement that the applicant or the

1 applicant's guardian or custodian attest that the information  
2 provided in the application is accurate to the best knowledge and  
3 belief of the applicant or the applicant's guardian or custodian.

4 (b) In assessing the income requirement for program  
5 eligibility, the department shall use the income information  
6 reported on the application and shall not require additional  
7 documentation.

8 (c) Any person who intentionally makes a false declaration as  
9 to his or her eligibility or any person who intentionally makes a  
10 false declaration as to eligibility on behalf of any other person  
11 seeking eligibility under this division for which that person is not  
12 eligible shall be guilty of a misdemeanor.

13 (d) Any person who intentionally makes a false declaration as  
14 to his or her eligibility or any person who intentionally makes a  
15 false declaration as to eligibility on behalf of any other person  
16 seeking eligibility under this division for which that person is not  
17 eligible may be denied a drug discount card under this program  
18 for up to one year from the date of the denial of coverage by the  
19 department.

20 (e) Upon determination of eligibility, the department shall  
21 mail the qualified resident a California Rx Plus Discount Card.

22 130507. (a) The department shall execute agreements with  
23 drug manufacturer patient assistance programs to provide a  
24 single point of entry for eligibility determination and claims  
25 processing for drugs available through those programs.

26 (b) The department shall develop a system to provide a  
27 participant under this division with the best discounts on  
28 prescription drugs that are available to the participant through  
29 this program or through a drug manufacturer patient assistance  
30 program.

31 (c) (1) The department may require an applicant to provide  
32 additional information to determine the applicant's eligibility for  
33 other discount card and patient assistance programs.

34 (2) The department shall not require an applicant to participate  
35 in a drug manufacturer patient assistance program or to disclose  
36 information that would determine the applicant's eligibility to  
37 participate in a drug manufacturer patient assistance program in  
38 order to participate in the program established pursuant to this  
39 division.

1 (d) In order to verify that California residents are being served  
2 by drug manufacturer patient assistance programs, the  
3 department shall require drug manufacturers to provide the  
4 department annually with all of the following information:

5 (1) The total value of the manufacturer's drugs provided at no  
6 or very low cost to California residents during the previous year.

7 (2) The total number of prescriptions or 30-day supplies of the  
8 manufacturer's drugs provided at no or very low cost to  
9 California residents during the previous year.

10 (3) The total number of prescriptions or 30-day supplies, and  
11 total value, of each of the manufacturer's brand name drugs  
12 provided at no or very low cost to California residents during the  
13 previous year.

14 (e) The California Rx Plus Discount Card issued pursuant to  
15 subdivision (e) of Section 130506 shall serve as a single point of  
16 entry for drugs available pursuant to subdivision (a) and shall  
17 meet all legal requirements for a uniform prescription drug card  
18 pursuant to Section 1363.03.

19  
20 CHAPTER 3. ADMINISTRATION AND SCOPE  
21

22 130515. (a) The department shall conduct an outreach  
23 program to inform California residents of their opportunity to  
24 participate in the California Rx Plus State Pharmacy Assistance  
25 Program. The department shall implement an outreach,  
26 education, and enrollment program with Health Insurance  
27 Counseling and Advocacy Program agencies, the California  
28 Department of Aging and other state agencies, local agencies,  
29 and nonprofit organizations that serve residents who may qualify  
30 for the program.

31 (b) The department shall implement a plan to prevent the  
32 occurrence of fraud in the program.

33 130516. (a) Any pharmacy licensed pursuant to Chapter 9  
34 (commencing with Section 4000) of Division 2 of the Business  
35 and Professions Code may participate in the program.

36 (b) Any drug manufacturer may participate in the program.

37 130517. (a) The amount a program participant pays for a  
38 drug through the program shall be equal to the participating  
39 provider's usual and customary charge or the pharmacy contract  
40 rate pursuant to subdivision (c), less a program discount for the

1 specific drug or an average discount for a group of drugs or all  
2 drugs covered by the program.

3 (b) In determining program discounts on individual drugs, the  
4 department shall take into account the rebates provided by the  
5 drug's manufacturer and the state's share of the discount.

6 (c) The department may contract with participating  
7 pharmacies for a rate other than the pharmacies' usual and  
8 customary rate.

9 130518. (a) The department shall negotiate drug rebate  
10 agreements with drug manufacturers to provide for discounts for  
11 prescription drugs purchased through the program.

12 (b) The department shall seek to obtain an initial rebate  
13 amount equal to or greater than the rebate calculated under the  
14 Medi-Cal rebate program pursuant to Section 14105.33 of the  
15 Welfare and Institutions Code.

16 (c) Upon receipt of a determination from the federal Centers  
17 for Medicare and Medicaid Services that the program is a state  
18 pharmaceutical assistance program as provided in Section  
19 130522, the department shall seek to contract for drug rebates  
20 that result in a net price lower than the Medicaid best price for  
21 drugs covered by the program.

22 (d) To obtain the most favorable discounts, the department  
23 may limit the number of drugs available through the program.

24 (e) All of the drug rebates negotiated pursuant to this section  
25 shall be used to reduce the cost of drugs purchased by  
26 participants in the program.

27 (f) Each drug rebate agreement shall do all of the following:

28 (1) Specify which of the manufacturer's drugs are included in  
29 the agreement.

30 (2) Permit the department to remove a drug from the  
31 agreement in the event of a dispute over the drug's utilization.

32 (3) Require the manufacturer to make a rebate payment to the  
33 department for each drug specified under paragraph (1)  
34 dispensed to a recipient.

35 (4) Require the rebate payment for a drug to be equal to the  
36 amount determined by multiplying the applicable per unit rebate  
37 by the number of units dispensed.

38 (5) Define a unit, for purposes of the agreement, in compliance  
39 with the standards set by the National Council of Prescription  
40 Drug Programs.



1 (6) Require the manufacturer to make the rebate payments to  
2 the department on at least a quarterly basis.

3 (7) Require the manufacturer to provide, upon the request of  
4 the department, documentation to validate that the per unit rebate  
5 provided complies with paragraph (4).

6 (8) Require the manufacturer to calculate and pay interest on  
7 late or unpaid rebates. The department may, by regulation,  
8 establish the date upon which the interest payments by drug  
9 manufacturers shall begin to accrue as well as any other  
10 regulations it deems necessary for the implementation of this  
11 paragraph.

12 (g) The department may collect prospective rebates from  
13 manufacturers for payment to pharmacies. The amount of the  
14 prospective rebate shall be contained in the drug rebate  
15 agreements executed pursuant to this section.

16 130519. (a) (1) The department may require prior  
17 authorization in the Medi-Cal program pursuant to Section 1927  
18 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) for  
19 any drug of a manufacturer that does not agree to provide rebates  
20 to the department for prescription drugs purchased under this  
21 division, to the extent the department determines *that* it is  
22 appropriate to do *so* in order to encourage manufacturer  
23 participation in the program, ~~and~~ to the extent permitted by  
24 federal law, and subject to any necessary federal approvals or  
25 waivers.

26 (2) In making a determination to require prior authorization in  
27 the Medi-Cal program pursuant to paragraph (1), the department  
28 shall ensure that there are as many single-source drugs within  
29 each therapeutic category or subcategory as the department  
30 determines necessary to meet the health needs of the Medi-Cal  
31 population. In no event shall a Medi-Cal beneficiary be denied  
32 continued use of a drug that is part of a prescribed therapy unless  
33 that drug is no longer prescribed for that beneficiary.

34 (b) The names of manufacturers that do and do not enter into  
35 rebate agreements with the department pursuant to this division  
36 shall be public information and shall be released to the public.

37 130520. Contracts entered into for purposes of this division  
38 are exempt from Part 2 (commencing with Section 10100) of  
39 Division 2 of the Public Contract Code. Contracts with

1 pharmacies and drug manufacturers may be entered into on a bid  
2 or nonbid basis.

3 130522. The department shall seek a determination from the  
4 federal Centers for Medicare and Medicaid Services that the  
5 program established pursuant to this division complies with the  
6 requirements for a state pharmaceutical assistance program  
7 pursuant to Section 1927 of the federal Social Security Act (42  
8 U.S.C. Sec. 1396r-8) and that discounts provided under the  
9 program are exempt from the Medicaid best price requirement.

10 130523. (a) The department shall deposit all payments the  
11 department receives pursuant to this division into the California  
12 Rx Plus Program Fund, which is hereby established in the State  
13 Treasury.

14 (b) Upon appropriation by the Legislature, moneys in the fund  
15 shall be used for the purpose of providing payment to  
16 participating pharmacies pursuant to Section 130517 and for  
17 defraying the costs of administering this division.  
18 Notwithstanding any other provision of law, no money in the  
19 fund is available for expenditure for any other purpose or for  
20 loaning or transferring to any other fund, including the General  
21 Fund.

22 (c) Notwithstanding Section 16305.7 of the Government Code,  
23 the fund shall also contain any interest accrued on moneys in the  
24 fund.

25 SEC. 2. No reimbursement is required by this act pursuant to  
26 Section 6 of Article XIII B of the California Constitution because  
27 the only costs that may be incurred by a local agency or school  
28 district will be incurred because this act creates a new crime or  
29 infraction, eliminates a crime or infraction, or changes the  
30 penalty for a crime or infraction, within the meaning of Section  
31 17556 of the Government Code, or changes the definition of a  
32 crime within the meaning of Section 6 of Article XIII B of the  
33 California Constitution.



# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: AB 75**

**VERSION: AMENDED MAY 26, 2005**

**AUTHOR: FROMMER**

**SPONSOR: FROMMER**

**RECOMMENDED POSITION:**

**SUBJECT: PHARMACEUTICAL ASSISTANCE PROGRAM**

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### **Existing Law:**

Establishes within the Department of Health Services (DHS) a prescription drug discount program for Medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

### **This Bill:**

1. Establishes the California Rx Plus State Pharmacy Assistance Program (Program) within DHS. (H&S 130501 Added)
2. Defines the terms: Program, Department (DHS), fund (California Rx Plus Program Fund), program, manufacturer (drug manufacturer), resident, and qualified resident. (H&S 130500 Added)
3. Establishes the criteria for a qualified resident as:
  - a. A resident of California who has a family income equal to or less than 400 percent of the federal poverty guidelines. (2005 - \$38,280 for an individual and \$77,400 for a family of four)
  - b. A family that incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of family income or whose total unreimbursed medical expenses equal fifteen percent or more of family income. (H&S 130500 Added)
4. Allows an individual enrolled in Medicare to participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare. (H&S 130505 Added)
5. Requires DHS to conduct an outreach program to inform California residents of their opportunity to participate in program. Requires DHS to coordinate outreach activities with the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program. (H&S 130515 Added)
6. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program and to seek rebates equal to or greater than Medi-Cal rebates. (H&S 130518 Added)
7. Requires that all of the drug rebates negotiated will be used to reduce the cost of drugs purchased by participants in the program. (H&S 130518 Added)

8. Establishes the California Rx Plus Program Fund, but does not appropriate funds to implement the program. (H&S 130523 Added)

9. Makes it a misdemeanor to falsify information to gain access to the program. Additionally, it bars a person for one year from the program if the person falsifies information to gain access to the program. (H&S 130506 Added)

### **Comment:**

**1) Author's Intent.** The author is concerned about the high cost of prescription drugs and the inability of uninsured individuals to pay for their medications.

**2) Cost of Prescription Drugs and the Uninsured.** In 2002, American consumers paid \$48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months thirty-five percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

**3) State Strategies for Reducing Cost of Drugs.** Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rhode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

### **4) Related Legislation.**

SB 19 (Ortiz) California Rx Program. This bill is sponsored by the Governor and would establish a state program to negotiate for lower price prescription drugs for lower income Californians. SB 19 failed to make it out of the Senate and is now a two-year bill.

## 5) Support / Opposition.

Support: AIDS Healthcare Foundation

Alzheimer's Association

American Federation of State, County and Municipal Employees

California Alliance for Retired Americans

California Federation of Labor

California Federation of Teachers

California Labor Federation

California Nurses Association

California Pharmacists Association

California Public Interest Research Group

Consumers Union

Health Access California

NAMI California (if amended)

Older Women's League of California

Retired Public Employees Association

Senior Action Network

Service Employees International Union

Opposition: BIOCUM

California Chamber of Commerce

Department of Health Services (unless amended)

National Association of Chain Drug Stores (unless amended)

Mental Health Association of California

Novartis Pharmaceuticals

Pharmaceutical Research and Manufacturers of America

Western Center on Law & Poverty

Wyeth Pharmaceuticals

## 6) History.

2005

June 28 In committee: Set, first hearing. Hearing canceled at the request of author.

June 15 Referred to Com. on HEALTH.

June 6 In Senate. Read first time. To Com. on RLS. for assignment.

June 2 Read third time, passed, and to Senate. (Ayes 43. Noes 34. Page 2141.)

May 27 Read second time. To third reading.

May 26 From committee: Amend, and do pass as amended. (Ayes 11. Noes 4.) (May 25). Read second time and amended. Ordered returned to second reading.

May 11 In committee: Set, first hearing. Referred to APPR. suspense file.

May 3 Re-referred to Com. on APPR.

May 2 Read second time and amended.

Apr. 28 From committee: Amend, and do pass as amended, and re-refer to Com. on APPR. (Ayes 7. Noes 1.) (April 26).

Apr. 20 Re-referred to Com. on B. & P.

Apr. 19 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.

Apr. 13 From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 9. Noes 2.) (April 12).

Apr. 6 Re-referred to Com. on HEALTH.

Apr. 5 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

Jan. 18 Referred to Coms. on HEALTH and B. & P.

Jan. 4 From printer. May be heard in committee February 3.

Jan. 3 Read first time. To print.

AMENDED IN SENATE APRIL 18, 2005  
AMENDED IN SENATE JANUARY 6, 2005

**SENATE BILL**

**No. 19**

**Introduced by Senator Ortiz  
(Principal coauthor: Senator Poochigian)**

December 6, 2004

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An act to add Division 112 (commencing with Section 130600) to the Health and Safety Code, relating to pharmacy—~~assistance~~, *assistance*, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 19, as amended, Ortiz. California Rx Program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug—~~manufactures~~ *manufacturers* are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California *State* Pharmacy Assistance Program (Cal Rx) under the oversight of the department. The bill would authorize the department to implement and administer Cal Rx through a contract with a 3rd-party vendor or utilizing existing health care service provider enrollment and payment mechanisms. The bill would require the department—~~or 3rd-party vendor~~ to attempt to negotiate—~~drug manufacturer~~ rebate agreements for Cal Rx with drug manufacturers. The bill would authorize any licensed pharmacy and any drug manufacturer, as defined, to provide services under Cal Rx. The bill would establish eligibility criteria and application procedures for California residents to participate in Cal Rx. The application process would require an applicant to attest to information provided

under penalty of perjury, which would expand the definition of an existing crime, thereby imposing a state-mandated local program. ~~The bill would authorize the department to terminate the program if any one of 3 determinations are made.~~

The bill would establish the California State Pharmacy Assistance Program Fund into which all payments received under Cal Rx would be deposited. The bill would continuously appropriate the fund to the department for purposes of Cal Rx.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote:  $\frac{2}{3}$ . Appropriation: yes. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Division 112 (commencing with Section  
2 130600) is added to the Health and Safety Code, to read:

3

4 DIVISION 112. CALIFORNIA STATE PHARMACY  
5 ASSISTANCE PROGRAM (CAL RX)

6

7 CHAPTER 1. GENERAL PROVISIONS

8

9 130600. This division shall be known, and may be cited, as  
10 the California State Pharmacy Assistance Program or Cal Rx.

11 130601. For the purposes of this division, the following  
12 definitions shall apply:

13 (a) "Benchmark price" means the price for an individual drug  
14 or aggregate price for a group of drugs offered by a manufacturer  
15 equal to the lowest commercial price for the individual drug or  
16 group of drugs.

17 (b) "Cal Rx" means the California State Pharmacy Assistance  
18 Program.

19 (c) "Department" means the State Department of Health  
20 Services.

1 (d) “Fund” means the California State Pharmacy Assistance  
2 Program Fund.

3 (e) “Inpatient” means a person who has been admitted to a  
4 hospital for observation, diagnosis, or treatment and who is  
5 expected to remain overnight or longer.

6 (f) (1) “Lowest commercial price” means the lowest purchase  
7 price for an individual drug, including all discounts, rebates, or  
8 free goods, available to any wholesale or retail commercial class  
9 of trade in California.

10 (2) Lowest commercial price excludes purchases by  
11 government entities, purchases pursuant to Section 340B of the  
12 federal Public Health Services Act (42 U.S.C. Sec. 256b), or  
13 nominal prices as defined in federal Medicaid drug rebate  
14 agreements.

15 (3) A purchase price provided to an acute care hospital or  
16 acute care hospital pharmacy may be excluded if the prescription  
17 drug is used exclusively for an inpatient of the hospital.

18 (4) Wholesale or retail commercial class of trade includes  
19 distributors, retail pharmacies, pharmacy benefit managers,  
20 health maintenance organizations, or any entities that directly or  
21 indirectly sell prescription drugs to consumers through licensed  
22 retail pharmacies, physician offices, or clinics.

23 (g) “Manufacturer” means a drug manufacturer as defined in  
24 Section 4033 of the Business and Professions Code.

25 (h) ~~“Manufacturers”~~ “*Manufacturer’s rebate*” means the rebate  
26 for an individual drug or aggregate rebate for a group of drugs  
27 necessary to make the price for the drug ingredients equal to or  
28 less than the applicable benchmark price.

29 (i) “*Multiple-source drug*” means the same drug in the same  
30 dosage form and strength manufactured by two or more  
31 manufacturers, which is approved by the United States Food and  
32 Drug Administration under provisions pertaining to the  
33 Abbreviated New Drug Applications (ANDA) process.

34 (j) “National Drug Code” or “NDC” means the unique  
35 10-digit, three-segment number assigned to each drug product  
36 listed under Section 510 of the federal Food, Drug, and Cosmetic  
37 Act (21 U.S.C. Sec. 360). This number identifies the labeler or  
38 vendor, product, and trade package.

39 (k) “Participating manufacturer” means a drug manufacturer  
40 that has contracted with the department to provide an individual



1 *drug or group of drugs for Cal Rx participants at a price that is*  
2 *equal to or lower than the benchmark price.*

3 (l) *“Participating pharmacy” means a pharmacy that has*  
4 *executed a pharmacy provider agreement with the department*  
5 *for Cal Rx.*

6 (m) *“Pharmacy contract rate” means the negotiated per*  
7 *prescription reimbursement rate for drugs dispensed to Cal Rx*  
8 *recipients.*

9 (n) *“Prescription drug” means any drug that bears the legend:*  
10 *“Caution: federal law prohibits dispensing without prescription,”*  
11 *“Rx only,” or words of similar import.*

12 (o) *“Private discount drug program” means a prescription drug*  
13 *discount card or manufacturer patient assistance program that*  
14 *provides discounted or free drugs to eligible individuals. For the*  
15 *purposes of this division, a private discount drug program is not*  
16 *considered insurance or a third-party payer program.*

17 (p) *“Recipient” means a resident that has completed an*  
18 *application and has been determined eligible for Cal Rx.*

19 (q) *“Resident” means a California resident pursuant to Section*  
20 *17014 of the Revenue and Taxation Code.*

21 ~~(m) “Third-party vendor” means a public or private entity~~  
22 ~~with whom the department contracts pursuant to subdivision (b)~~  
23 ~~of Section 130602, which may include a pharmacy benefit~~  
24 ~~administration or pharmacy benefit management company.~~

25 (r) *“Therapeutic category” means a drug or a grouping of*  
26 *drugs determined by the department to have similar attributes*  
27 *and to be alternatives for the treatment of a specific disease or*  
28 *condition.*

29 130602. (a) There is hereby established the California State  
30 Pharmacy Assistance Program or Cal Rx.

31 (b) The department shall provide oversight of Cal Rx. To  
32 implement and administer Cal Rx, the department may contract  
33 with a third-party vendor or utilize existing health care service  
34 provider enrollment and payment mechanisms, including the  
35 Medi-Cal program’s fiscal intermediary.

36 (c) Any resident may enroll in Cal Rx if determined eligible  
37 pursuant to Section 130605.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCESS

130605. (a) To be eligible for Cal Rx, an individual shall meet all of the following requirements at the time of application and reapplication for the program:

(1) Be a resident.

(2) Have family income, as reported pursuant to Section 130606, that does not exceed 300 percent of the federal poverty guidelines, as revised annually by the United States Department of Health and Human Services in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902), as amended.

(3) Not have outpatient prescription drug coverage paid for in whole or in part by any of the following:

(A) A third-party payer. *An individual who has reached the annual limit on his or her outpatient prescription drug coverage provided by a third-party payer shall also be eligible for Cal Rx if he or she meets the eligibility requirements pursuant to paragraphs (1) and (2).*

(B) The Medi-Cal program.

(C) The children's health insurance program.

~~(D) The disability medical assistance program.~~

~~(E)~~

*(D) Another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. Notwithstanding any other provision of this division to the contrary, an individual enrolled in Medicare may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare: extent allowed by federal law and consistent with federal state pharmacy assistance program standards, for prescription drugs not covered by Medicare prescription drug coverage or with respect to an individual responsible for paying 100 percent of the cost of prescription drugs under the coverage gap provisions of the Medicare Program prescription drug benefit.*

(4) Not have had outpatient prescription drug coverage specified in paragraph (3) during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, unless any of the following applies:

1 (A) The third-party payer that paid all or part of the coverage  
2 filed for bankruptcy under the federal bankruptcy laws.

3 (B) The individual is no longer eligible for coverage provided  
4 through a retirement plan subject to protection under the  
5 Employee Retirement Income Security Act of 1974 (29 U.S.C.  
6 Sec. 1001), as amended.

7 (C) The individual is no longer eligible for the Medi-Cal  
8 program, children's health insurance program, or disability  
9 medical assistance program.

10 *(D) The individual is no longer eligible for prescription drug*  
11 *coverage due to loss of employment and is not eligible for*  
12 *continued prescription drug coverage through the previous*  
13 *employer.*

14 (b) Application and an annual reapplication for Cal Rx shall be  
15 made pursuant to subdivision (d) of Section 130606. An  
16 applicant, or a guardian or custodian of an applicant, may apply  
17 or reapply on behalf of the applicant and the applicant's spouse  
18 and children.

19 130606. (a) The department or third-party vendor shall  
20 develop an application and reapplication form for the  
21 determination of a resident's eligibility for Cal Rx.

22 (b) The application, at a minimum, shall do all of the  
23 following:

24 (1) Specify the information that an applicant or the applicant's  
25 representative must include in the application.

26 (2) Require that the applicant, or the applicant's guardian or  
27 custodian, attest that the information provided in the application  
28 is accurate to the best knowledge and belief of the applicant or  
29 the applicant's guardian or custodian.

30 (3) Include a statement printed in bold letters informing the  
31 applicant that knowingly making a false statement is punishable  
32 under penalty of perjury.

33 (4) Specify that the application and annual reapplication fee  
34 due upon submission of the ~~applicable form~~ *application form*  
35 *through a pharmacy, physician office, or clinic* is fifteen dollars  
36 (\$15).

37 (c) In assessing the income requirement for Cal Rx eligibility,  
38 the department shall use the income information reported on the  
39 application and not require additional documentation.

1 (d) Application and annual reapplication may be made at any  
2 pharmacy, physician office, or clinic participating in Cal Rx;  
3 ~~through a Web site or call center staffed by trained operators~~  
4 ~~approved by the department, or through the third-party vendor.~~

5 A pharmacy, physician office, clinic, or third-party vendor  
6 completing the application shall keep the application fee as  
7 reimbursement for its processing costs. If it is determined that the  
8 applicant is already enrolled in Cal Rx, the fee shall be returned  
9 to the applicant and the applicant shall be informed of his or her  
10 current status as a recipient.

11 (e) *Application and annual reapplication may be made*  
12 *through a Web site or call center staffed by trained operators*  
13 *approved by the department.*

14 (f) The department or third-party vendor shall utilize a secure  
15 electronic application process that can be used by a pharmacy,  
16 physician office, or clinic, by a Web site, by a call center staffed  
17 by trained operators, or through the third-party vendor to enroll  
18 applicants in Cal Rx.

19 ~~(f) During normal~~

20 (g) *During the department's regular business hours, the*  
21 *department or third-party vendor shall make a determination of*  
22 *eligibility within four hours of receipt by Cal Rx of a completed*  
23 *application. The department or third-party vendor shall mail the*  
24 *recipient an identification card no later than four days after*  
25 *eligibility has been determined.*

26 ~~(g)~~

27 (h) For applications submitted through a pharmacy, the  
28 department or third-party vendor may issue a recipient  
29 identification number for eligible applicants to the pharmacy for  
30 immediate access to Cal Rx.

31 (i) *Any person that signs and dates an application shall certify*  
32 *that the information in the application is true under penalty of*  
33 *perjury.*

34 130607. (a) *The department shall encourage a participating*  
35 *manufacturer to maintain the level of private discount drug*  
36 *programs provided at a comparable level to that provided prior*  
37 *to the enactment of this division. To the extent possible, the*  
38 *department shall encourage a participating manufacturer to*  
39 *simplify the application and eligibility processes for its private*  
40 *discount drug program.*

1 (b) The department or third-party vendor shall attempt to  
2 execute agreements with private discount drug programs to  
3 provide a single point of entry for eligibility determination and  
4 claims processing for drugs available in those private discount  
5 drug programs.

6 ~~(b)~~

7 (c) (1) Private discount drug programs may require an  
8 applicant to provide additional information, beyond that required  
9 by Cal Rx, to determine the applicant's eligibility for discount  
10 drug programs.

11 (2) An applicant shall not be, under any circumstances,  
12 required to participate in, or to disclose information that would  
13 determine the applicant's eligibility to participate in, private  
14 discount drug programs in order to participate in Cal Rx.

15 (3) Notwithstanding paragraph (2), an applicant may  
16 voluntarily disclose or provide information that may be necessary  
17 to determine eligibility for participation in a private drug  
18 discount program.

19 ~~(c)~~

20 (d) For those drugs available pursuant to subdivision-~~(a)~~ (b),  
21 the department or third-party vendor shall develop a system that  
22 provides a recipient with the best prescription drug discounts that  
23 are available to them through Cal Rx or through private discount  
24 drug programs.

25 ~~(d)~~

26 (e) The recipient identification card issued pursuant to  
27 subdivision-~~(g)~~ (h) of Section 130606 shall serve as a single point  
28 of entry for drugs available pursuant to subdivision-~~(a)~~ (b) and  
29 shall meet all legal requirements for a uniform prescription drug  
30 card pursuant to Section 1363.03.

31

### 32 CHAPTER 3. ADMINISTRATION AND SCOPE

33

34 130615. (a) To the extent that funds are available, the  
35 department shall conduct outreach programs to inform residents  
36 about Cal Rx and private drug discount programs available  
37 through the single point of entry as specified in subdivisions-~~(a)~~  
38 (b) and-~~(d)~~ (e) of Section 130607. No outreach material shall  
39 contain the name or likeness of a drug. The name of the  
40 organization sponsoring the material pursuant to subdivision (b)

1 may appear on the material once and in a font no larger than 10  
2 point.

3 (b) The department may accept on behalf of the state any gift,  
4 bequest, or donation of outreach services or materials to inform  
5 residents about Cal Rx. Neither Section 11005 of the  
6 Government Code, nor any other law requiring approval by a  
7 state officer of a gift, bequest, or donation shall apply to these  
8 gifts, bequests, or donations. For purposes of this section,  
9 outreach services may include, but shall not be limited to,  
10 coordinating and implementing outreach efforts and plans.  
11 Outreach materials may include, but shall not be limited to,  
12 brochures, pamphlets, fliers, posters, advertisements, and other  
13 promotional items.

14 (c) An advertisement provided as a gift, bequest, or donation  
15 pursuant to this section shall be exempt from Article 5  
16 (commencing with Section 11080) of Chapter 1 of Part 1 of  
17 Division 3 of Title 2 of the Government Code.

18 *(d) The department may negotiate a contract with any*  
19 *manufacturer to provide funds as grants to nonprofit programs*  
20 *pursuant to Division 2 (commencing with Section 5000) of Title 1*  
21 *of the Corporations Code, for the purpose of conducting*  
22 *outreach for Cal Rx.*

23 130616. (a) Any pharmacy licensed pursuant to Article 7  
24 (commencing with Section 4110) of Chapter 9 of Division 2 of  
25 the Business and Professions Code may participate in Cal Rx.

26 (b) Any manufacturer, as defined in subdivision (g) of Section  
27 130601, may participate in Cal Rx.

28 130617. (a) This division shall apply only to prescription  
29 drugs dispensed to noninpatient recipients.

30 (b) The amount a recipient pays for a drug within Cal Rx shall  
31 be equal to the pharmacy contract rate pursuant to subdivision  
32 (c), plus a dispensing fee that shall be negotiated as part of the  
33 rate pursuant to subdivision (c), less the applicable ~~manufacturers~~  
34 *manufacturer's* rebate.

35 (c) The department or third-party vendor may contract with  
36 participating pharmacies for a rate other than the pharmacist's  
37 usual and customary rate. However, the department must approve  
38 the contracted rate of a third-party vendor.

1 (d) The department or third-party vendor shall provide a  
2 claims processing system that complies with all of the following  
3 requirements:

4 (1) Charges a price that meets the requirements of subdivision  
5 (b).

6 (2) Provides the pharmacy with the dollar amount of the  
7 discount to be returned to the pharmacy.

8 (3) Provides a single point of entry for access to private  
9 discount drug programs pursuant to Section 130607.

10 (4) Provides drug utilization review warnings to pharmacies  
11 consistent with the drug utilization review standards outlined in  
12 Section 1927 of the federal Social Security Act (42 U.S.C. Sec.  
13 1396r-8(g)).

14 (e) The department or third-party vendor shall pay a  
15 participating pharmacy the discount provided to recipients  
16 pursuant to subdivision (b) by a date that is not later than two  
17 weeks after the claim is received.

18 (f) The department or third-party vendor shall develop a  
19 program to prevent the occurrence of fraud in Cal Rx.

20 (g) The department or third-party vendor shall develop a  
21 mechanism for recipients to report problems or complaints  
22 regarding Cal Rx.

23 *(h) A participating pharmacy is not precluded from offering*  
24 *the recipient a pharmacy contract reimbursement rate pursuant*  
25 *to subdivision (c) for prescription drugs produced by*  
26 *manufacturers not participating in Cal Rx.*

27 130618. (a) In order to secure the discount required pursuant  
28 to subdivisions (b) and (c) of Section 130617, ~~the department or~~  
29 ~~third-party vendor shall attempt to negotiate drug department~~  
30 *shall attempt to negotiate manufacturer rebate agreements for*  
31 *Cal Rx with drug manufacturers. The department shall pursue*  
32 *manufacturer rebate agreements for all drugs in each*  
33 *therapeutic category.*

34 ~~(b) Each drug rebate agreement shall do all of the following:~~

35 *(b) Each participating manufacturer rebate agreement*  
36 *executed pursuant to this division shall do all of the following:*

37 (1) Specify which of the *participating* manufacturer's drugs  
38 are included in the agreement.

39 (2) Permit the department to remove a drug from the  
40 agreement in the event of a dispute over the drug's utilization.

1 (3) Require the *participating* manufacturer to make a rebate  
2 payment to the department for each drug specified under  
3 paragraph (1) dispensed to a recipient.

4 (4) Require the rebate payment for a drug to be equal to the  
5 amount determined by multiplying the applicable per unit rebate  
6 by the number of units dispensed.

7 (5) Define a unit, for purposes of the agreement, in compliance  
8 with the standards set by the National Council of Prescription  
9 Drug Programs.

10 (6) Require the *participating* manufacturer to make the rebate  
11 payments to the department on at least a quarterly basis.

12 (7) Require the *participating* manufacturer to provide, upon  
13 the request of the department, documentation to validate that the  
14 per unit rebate provided complies with paragraph (4).

15 ~~(8) Permit a~~

16 (8) *Require the participating manufacturer to report to the*  
17 *department the lowest commercial price at the NDC level for*  
18 *each drug available through Cal Rx.*

19 (9) *Require the participating manufacturer to pay interest on*  
20 *late or unpaid rebates pursuant to subdivision (h).*

21 (10) *Permit a participating* manufacturer to audit claims for  
22 the drugs the manufacturer provides under Cal Rx. Claims  
23 information provided to manufacturers shall comply with all  
24 federal and state privacy laws that protect a recipient's health  
25 information.

26 (11) *Contain provisions for the timely reconciliation and*  
27 *payment of rebates and interest penalties on disputed units.*

28 (12) *Permit the department to audit or review participating*  
29 *manufacturer records and contracts as necessary to implement*  
30 *this division.*

31 (c) To obtain the most favorable discounts, the department  
32 may limit the number of drugs available within Cal Rx.

33 (d) *To obtain the most favorable discounts on multiple-source*  
34 *drugs, the department may contract with private or public*  
35 *purchasing groups.*

36 (e) The entire amount of the drug rebates negotiated pursuant  
37 to this section shall go to reducing the cost to Cal Rx recipients  
38 of purchasing drugs. The Legislature shall annually appropriate  
39 an amount to cover the state's share of the discount provided by  
40 this section.



1     ~~(e)~~

2     (f) The department or third-party vendor may collect  
3 prospective rebates from *participating* manufacturers for  
4 payment to pharmacies. The amount of the prospective rebate  
5 shall be contained in drug rebate agreements executed pursuant  
6 to this section.

7     ~~(f) Drug rebate contracts negotiated by the third-party vendor~~  
8 ~~shall be subject to review by the department. The department~~  
9 ~~may cancel a contract that it finds not in the best interests of the~~  
10 ~~state or Cal Rx recipients.~~

11     (g) The third-party vendor may directly collect rebates from  
12 manufacturers in order to facilitate the payment to pharmacies  
13 pursuant to subdivision (e) of Section 130617. The department  
14 shall develop a system to prevent diversion of funds collected by  
15 the third-party vendor.

16     (h) (1) *A participating manufacturer shall calculate and pay*  
17 *interest on late or unpaid rebates.*

18     (2) *Interest described in paragraph (1) shall begin accruing*  
19 *38 calendar days from the date of mailing the quarterly invoice,*  
20 *including supporting utilization data sent to the manufacturer.*  
21 *Interest shall continue to accrue until the date the*  
22 *manufacturer's payment is mailed.*

23     (3) *Interest rates and calculations for purposes of this*  
24 *subdivision shall be at \_\_\_\_ percent.*

25     (i) *A participating manufacturer shall clearly identify all*  
26 *rebates, interest, and other payments, and payment transmittal*  
27 *forms for Cal Rx, in a manner designated by the department.*

28     130619. (a) The department or third-party vendor shall  
29 generate a monthly report that, at a minimum, provides all of the  
30 following:

31     (1) Drug utilization information.

32     (2) Amounts paid to pharmacies.

33     (3) Amounts of rebates collected from manufacturers.

34     (4) A Summary of the problems or complaints reported  
35 regarding Cal Rx.

36     (b) Information provided in paragraphs (1), (2), and (3) of  
37 subdivision (a) shall be at the national drug code level.

38     130620. (a) The department or third-party vendor shall  
39 deposit all payments received pursuant to Section 130618 into

1 the California State Pharmacy Assistance Program Fund, which  
2 is hereby established in the State Treasury.

3 (b) Notwithstanding Section 13340 of the Government Code,  
4 moneys in the fund are hereby appropriated to the department  
5 without regard to fiscal years for the purpose of providing  
6 payment to participating pharmacies pursuant to Section 130617  
7 and for defraying the costs of administering Cal Rx.  
8 Notwithstanding any other provision of law, no money in the  
9 fund is available for expenditure for any other purpose or for  
10 loaning or transferring to any other fund, including the General  
11 Fund.

12 (c) *Notwithstanding Section 16305.7 of the Government Code,*  
13 *any interest earned on any rebates collected from participating*  
14 *manufacturers on drugs purchased through Cal Rx implemented*  
15 *pursuant to this chapter shall be deposited in the fund exclusively*  
16 *to cover costs related to the purchase of drugs through Cal Rx.*

17 130621. The department may hire any staff needed for the  
18 implementation and oversight of Cal Rx.

19 130622. The department shall seek and obtain confirmation  
20 from the federal Centers for Medicare and Medicaid Services that  
21 Cal Rx complies with the requirements for a state pharmaceutical  
22 assistance program pursuant to Section 1927 of the federal Social  
23 Security Act (42 U.S.C. Sec. 1396r-8) and that discounts  
24 provided under the program are exempt from Medicaid best price  
25 requirements.

26 130623. (a) Contracts and change orders entered into  
27 pursuant to this division and any project or systems development  
28 notice shall be exempt from all of the following:

29 (1) The competitive bidding requirements of State  
30 Administrative Manual Management Memo 03-10.

31 (2) Part 2 (commencing with Section 10100) of Division 2 of  
32 the Public Contract Code.

33 (3) Article 4 (commencing with Section 19130) of Chapter 5  
34 of Part 2 of Division 5 of the Government Code.

35 (b) Change orders entered into pursuant to this division shall  
36 not require a contract amendment.

37 ~~130624. The department may terminate Cal Rx if the~~  
38 ~~department makes any one of the following determinations:~~

39 (a) ~~That there are insufficient discounts to participants to make~~  
40 ~~Cal Rx viable.~~

1     ~~(b) That there are an insufficient number of applicants for Cal~~  
2     ~~Rx.~~

3     ~~(c) That the department is unable to find a responsible~~  
4     ~~third-party vendor to administer Cal Rx.~~

5     ~~(c) Drug rebate contracts entered into pursuant to this~~  
6     ~~division are exempt from disclosure under the California Public~~  
7     ~~Records Act (Chapter 3.5 (commencing with Section 6250) of~~  
8     ~~Division 7 of Title 1 of the Government Code).~~

9     130625. Notwithstanding Chapter 3.5 (commencing with  
10    Section 11340) of Part 1 of Division 3 of Title 2 of the  
11    Government Code, the director may implement this division in  
12    whole or in part, by means of a provider bulletin or other similar  
13    instructions, without taking regulatory action.

14    SEC. 2. No reimbursement is required by this act pursuant to  
15    Section 6 of Article XIII B of the California Constitution because  
16    the only costs that may be incurred by a local agency or school  
17    district will be incurred because this act creates a new crime or  
18    infraction, eliminates a crime or infraction, or changes the  
19    penalty for a crime or infraction, within the meaning of Section  
20    17556 of the Government Code, or changes the definition of a  
21    crime within the meaning of Section 6 of Article XIII B of the  
22    California Constitution.



# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: SB 19**

**VERSION: AMENDED APRIL 18, 2005**

**AUTHOR: ORTIZ**

**SPONSOR: DEPT. OF HEALTH SERVICE  
GOVERNOR**

**RECOMMENDED POSITION:**

**SUBJECT: CALIFORNIA Rx PROGRAM**

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### **Existing Law:**

Establishes within the Department of Health Services (DHS) a prescription drug discount program for Medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

### **This Bill:**

1. Establishes the California State Pharmacy Assistance Program (Cal Rx, program) within the Department of Health Services (DHS). (H&S 130600 Added)
2. Permits DHS to contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. (H&S 130602 Added)
3. Defines the terms: benchmark price, Cal Rx, fund, inpatient, lowest commercial price, manufacturer, manufacturer's rebate, prescription drug, private discount drug program, recipient, resident, third-party vendor, multiple-source drug, national drug code, participating manufacturer, participating pharmacy, pharmacy contract rate, and therapeutic category. (H&S 130600 Added)
4. Establishes eligibility criteria for the program as:
  - a. A resident of California who has a family income does not exceed 300 percent of the federal poverty guidelines. (2005 - \$28,710 for an individual and \$58,050 for a family of four)
  - b. A family that does not have outpatient prescription drug coverage paid for in whole or in part by any of the following: a third-party payer, the Medi-Cal program, the children's health insurance program, or another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. (H&S 130605 Added)
5. Set a yearly fee of \$15 for application or reapplication for the program. (H&S 130606 Added)
6. Requires DHS or third party vendor to establish a Web site and call center to use for applying for the program. Additionally requires DHS or third party vendor to determine eligibility for the program within four hours of receipt of a completed application. (H&S 130606 Added)

7. Permits DHS to conduct an outreach program to inform California residents of their opportunity to participate in program, if funds are available. (H&S 130615 Added)

8. Requires DHS to negotiate drug rebate agreements with drug manufacturer's to provide for discounts for prescription drugs purchased through the program. (H&S 130618 Added)

9. Sets the amount a recipient pays for a drug within program as equal to the pharmacy contract rate, plus a dispensing fee that shall be negotiated by DGS, less the applicable manufacturer's rebate. (H&S 130616 Added)

### **Comment:**

**1) Author's Intent.** This bill is sponsored by the Governor and is in response to last year's veto of SB 1149 (Ortiz 2004). In his veto message the Governor stated, "A top priority of my Administration is to provide access to affordable prescription drugs. However, importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward California Rx that seeks to provide real assistance to these Californians. California Rx represents an approach that harnesses the purchasing power of low-income seniors and uninsured Californians up to 300% of the federal poverty level (\$28,710 for an individual and \$58,050 for a family of four) to secure meaningful discounts in prescription drug costs. My Administration has begun negotiations with pharmaceutical companies regarding their participation in California Rx."

A fact sheet issued by the author's office states "In addition to the discounted drugs available to Cal Rx participants, Governor Schwarzenegger has secured a commitment from the Pharmaceutical Researchers and Manufacturers Association (PhRMA) to provide \$10 million over the next two fiscal years to fund a clearinghouse to publicize and help Californians enroll in manufacturers' free and discount programs. The clearinghouse will provide Internet access and a toll-free multi-lingual call center to help thousands of Californians receive prescription drugs absolutely free, thereby saving them hundreds of millions of dollars per year. This element of the program does not require legislation and will begin operating in Spring 2005."

**2) Cost of Prescription Drugs and the Uninsured.** In 2002, American consumers paid \$48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months thirty-five percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

**3) State Strategies for Reducing Cost of Drugs.** Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rhode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

#### **4) Related Legislation.**

AB 75 (Frommer) Pharmaceutical Assistance Program, would establish the California Rx Plus State Pharmacy Assistance Program within DHS. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program. The measure establishes eligibility for the program for families with incomes equal to or less than 400 percent of the federal poverty guidelines.

#### **5) Support / Opposition.**

Support: State Department of Health Services (sponsor)

- AARP
- AIDS Healthcare Foundation
- Alzheimer's Association
- American Russian Medical Association
- Asthma & Allergy Foundation of America
- BayBio
- BIOCOM
- CA Academy of Family Physicians
- CA Arthritis Foundation Council
- CA Black Chamber of Commerce
- CA Council of Community Mental Health Agencies
- CA Healthcare Institute
- CA Hepatitis C Task Force
- CA Latino Medical Association
- CA Medical Association
- CA Pharmacists Association
- CA Psychiatric Association
- CA Society of Health-System Pharmacists
- Down Syndrome Information Alliance
- Epilepsy Foundation
- Generic Pharmaceutical Association (if amended)
- Gray Panthers California (if amended)
- Hemophilia Council of California
- Hispanic-American Allergy Asthma and Immunology Association
- Lambda Letters Project
- Mental Health Association in California
- NAMI California
- National Multiple Sclerosis Society - California Action Network
- Novartis

Osteopathic Physicians and Surgeons of California  
Pharmaceutical Research and Manufacturers of America  
TMJ Society of California

Opposition: California Alliance for Retired Americans

California Federation of Teachers  
California School Employees Association, AFL-CIO  
International Alliance of Theatrical Stage Employees, Moving Picture Technicians, Artists, and Allied Crafts of the United States  
Amalgamated Transit Union Local 1555  
Unless American Federation of Government Employees, Local 1061  
American Federation of State, County, & Municipal Employees  
American Federation of Television and Radio Arts  
Butchers' Union Local 120  
CA Conference Board of the Amalgamated Transit Union  
CA Conference of Machinists  
CA Labor Federation,  
CA Nurses Association  
CA Professional Firefighters  
CA Public Interest Research Group  
CA Teamsters Public Affairs Council  
Central Labor Council of Butte, Contra Costa, and Glenn Counties  
Consumer Federation of California  
Communications Workers of America (CWA), Local 9412  
CWA, Locals 9415, 9423, 9431, 9503, and 9586  
Engineers and Scientists of California Local 20, IFPTE  
Graphic Communications Union, Local 583  
Greenlining Institute  
Health Access California  
Industrial, Technical and Professional Employees Union, Local 4873  
International Alliance of Theatrical Stage Employees, Local 16  
International Association of Machinists and Aerospace Workers, District Lodge 947  
International Brotherhood of Electrical Workers (IBEW), Local 6 IBEW, Locals 45, 302, 441 and 569  
International Cinematographers Guild Local 600  
Ironworkers Locals 433 and 509  
Kern County Fire Fighters Union Inc.  
Laborers' International Union of North America  
Laborers' International Union of North America, Local 89  
League of United Latin American Citizens  
National Association of Broadcast Employees and Technicians, Local 53  
National Association of Chain Drug Stores  
National Association of Letter Carriers, Golden Gate Branch 214, AFL-CIO  
Northern California District Council - ILWU  
Office of Professional Employees International Union, AFL-CIO, CLC  
Orange County Central Labor Council, AFL-CIO  
Plumbers and Pipefitters UA, Local 62  
Professional and Technical Engineers, Local 21, IFPTE  
Professional Musicians, Local 47  
Sailors' Union of the Pacific  
San Diego Imperial Counties Labor Council, AFL-CIO  
San Francisco Labor Council, AFL-CIO  
San Mateo Building and Construction Trades Council

San Mateo County Central Labor Council Santa Clara & San Benito Counties  
 Building & Construction Trades Council  
 Senior Action Network  
 Service Employees International Union (SEIU), AFL-CIO  
 SEIU, Locals 660, 1280, and 2028  
 SEIU of United Healthcare Workers - West  
 Sheet Metal Workers' International Association Local Unions 104 and 206  
 Southern California District Council of Laborers  
 Strategic Committee of Public Employees, Laborers International Union  
 Teamsters Local Unions 683 and 896  
 Teamsters Locals 912 and 853  
 Teamsters Union Locals 572, 601, and 630  
 Transport Workers Union of America, AFL- CIO  
 Tri-Counties Central Labor Council  
 UFCW Locals 428, 1428, 1442, and 1179 UNITE-HERE! AFL-CIO UNITE-HERE! Locals 19 and 49  
 United Professional Firefighters of Contra Costa County, IAFF Local 1230  
 United Teachers Los Angeles

## 6) History.

2005

May 4	Hearing postponed by committee.
Apr. 28	Set for hearing May 4 pending suspension of rules.
Apr. 27	Set, first hearing. Failed passage in committee. (Ayes 5. Noes 5. Page 845.) Reconsideration granted.
Apr. 21	Set for hearing April 27.
Apr. 20	Hearing postponed by committee.
Apr. 18	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Apr. 14	Set for hearing April 20.
Apr. 13	Testimony taken. Hearing postponed by committee.
Mar. 17	Set for hearing April 13.
Jan. 27	To Com. on HEALTH.
Jan. 6	To Com. on RLS. From committee with author's amendments. Read second time. Amended. Re-referred to committee.

2004

Dec. 7	From print. May be acted upon on or after January 6.
Dec. 6	Introduced. Read first time. To Com. on RLS. for assignment. To print.



AMENDED IN ASSEMBLY JUNE 21, 2005

AMENDED IN SENATE APRIL 28, 2005

AMENDED IN SENATE APRIL 11, 2005

**SENATE BILL**

**No. 380**

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**Introduced by Senator Alquist**

February 17, 2005

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An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 380, as amended, Alquist. Drugs: adverse event reporting.

The Sherman Food, Drug and Cosmetics Law provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics under the administration of the State Department of Health Services. A violation of these provisions is a crime.

This bill would require a licensed health professional and a health facility to report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration (FDA), using the FDA 3500 Voluntary form developed by the FDA for MedWatch. The bill would prohibit a licensed health professional or health facility that violates this provision from being subject to the existing penalties and remedies of the Sherman Food, Drug and Cosmetics Law or any other provision of law.

Vote: majority. Appropriation: no. Fiscal committee: no.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. The Legislature finds and declares all of the  
2 following:

3 (a) The federal Food and Drug Administration (FDA) operates  
4 a voluntary reporting system for adverse drug reactions known as  
5 the MedWatch system.

6 (b) The FDA currently estimates that only 10 percent of the  
7 adverse drug reactions or events that occur each year are reported  
8 to the FDA.

9 (c) Given the prevalence of pharmaceuticals and their use for  
10 treatment of hundreds of chronic diseases and conditions, and  
11 given recent highly publicized instances of commonly used  
12 prescription drugs being taken off the market due to safety  
13 concerns that were discovered after the drugs were approved for  
14 use, the systematic underreporting of adverse drug events  
15 represents a serious public health problem.

16 (d) Requiring licensed health professionals of organizations to  
17 report adverse drug events to the FDA would increase the  
18 amount of data available to the FDA about adverse drug  
19 reactions, thereby enabling the FDA to discern problems with  
20 drugs that arise after they are approved and to take action to  
21 protect the public health in a more timely manner.

22 SEC. 2. Article 7 (commencing with Section 111657) is  
23 added to Chapter 6 of Part 5 of Division 104 of the Health and  
24 Safety Code, to read:

25  
26 Article 7. Adverse Event Reporting  
27

28 111657. (a) A licensed health professional, including, but not  
29 limited to, a physician and surgeon, dentist, or pharmacist, and a  
30 health facility, including, but not limited to, a hospital or clinic,  
31 shall report all suspected serious adverse drug events that are  
32 spontaneously discovered or observed in medical practice to  
33 MedWatch, the drug safety information and adverse event  
34 reporting program operated by the federal Food and Drug  
35 Administration.

36 (b) For purposes of this section, serious adverse drug events  
37 shall include adverse health outcomes involving patients that  
38 result in death, life-threatening conditions, hospitalization,

1 disability, congenital anomaly, or required intervention to  
2 prevent permanent impairment or damage.

3 (c) Any health professional or health facility that is required to  
4 report an adverse drug event pursuant to this section shall do so  
5 using the FDA 3500 Voluntary form developed by the federal  
6 Food and Drug Administration for MedWatch.

7 111658. A licensed health professional or health facility that  
8 violates any provision of this article shall not be subject to the  
9 penalties and remedies outlined in Chapter 8 (commencing with  
10 Section 111825) or any other provision of law. *Nothing in this*  
11 *section affects otherwise existing duties, rights, or remedies*  
12 *under the law.*

O



# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: SB 380**

**VERSION: AMENDED APRIL 28, 2005**

**AUTHOR: ALQUIST**

**SPONSOR: SENIOR CITIZENS, SO. CAL**

**RECOMMENDED POSITION: NO POSITION**

**SUBJECT: DRUGS: ADVERSE EVENT REPORTING**

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### **Existing Law:**

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers to report adverse drug reactions.

### **This Bill:**

- 1) Requires a licensed health professional, (a physician and surgeon, dentist, or pharmacist), and a health facility, (a hospital or clinic), to report all suspected serious adverse drug events that are spontaneous or observed in medical practice to the FDA's MedWatch program.
- 2) Requires the report to be made using FDA 3500, Voluntary form.
- 3) Defines a serious adverse drug events as, adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.
- 4) Provides that a person or health facility that violates any provision of the measure would not be subject to penalties and remedies in H&S 111825 or any other provisions in law. (Penalties under H&S 111825 are imprisonment for not more than one year in the county jail or a fine of not more than \$1,000, or both the imprisonment and fine.)

(H&S 111657 Added)

### **Comment:**

- 1) **Author's Intent.** The author is concerned that the FDA may not be receiving enough information about adverse drug reactions to make informed decisions to protect the public health.
- 2) **Enforcement.** This bill lacks language that would make the bill enforceable. There is no way to know how many adverse drug reactions a health professional observes each year. Consequently this bill would be impossible to enforce. Additionally, it is unclear how each regulatory board would know that an event should have been reported, but wasn't.
- 3) **FDA's MedWatch Program.** MedWatch is a voluntary reporting program run by the FDA that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.

Reporting is done on line, by phone, or by submitting the MedWatch 3500 form by mail or fax. The FDA disseminates medical product safety alerts, recalls, withdrawals, and important labeling changes to the medical community and the general public via its web site and the Med Watch E-list.

**4) Drugmakers Plans for Voluntary Disclosure on the Internet.** Reuters News reported on May 16, 2005 that the pharmaceutical industry plans to launch a global website in September 2005, pooling information on ongoing and completed clinical trials. Additionally, in January 2005, drugmakers in the United States, Europe, and Japan agreed on a voluntary code to publish detailed clinical trials data. Data would be available through a single website with links to company websites and other commercial and government-sponsored websites containing information provided by firms. The voluntary code is backed by Pfizer Inc, GlaxoSmithKline Plc, Merck, AstraZeneca Plc, Novartis AG and Sanofi-Aventis SA.

**5) Other Legislation.** Two other bills dealing with drug safety and reporting requirements have been introduced this session.

AB 71 (Chan) Office of California Drug Safety Watch, would require DHS to 1) establish a central repository of information about the safety and effectiveness of prescription drugs; and 2) disseminate information to health care professionals and consumers through a Web site that would include links to other relevant web-based information that has been professionally reviewed and approved.

SB 329 (Cedillo) California Prescription Drug Safety and Effectiveness Commission. This is a spot bill and will be amended for other purposes.

**6) Federal Legislation.** On May 4, 2005, Congressman Hinchey introduced H.R. 2090, the Food and Drug Administration Improvement Act of 2005. This bill would: 1) establish within the FDA a Center for Postmarket Drug Safety and Effectiveness to monitor all approved drugs as well as all advertisements and promotions associated with those products; 2) prohibit the FDA from collecting fees paid by companies it regulates and instead, deposit those funds into the general fund of the Treasury; 3) empower the FDA with the authority to mandate that companies conduct post-marketing studies of FDA-approved drugs; and 4) enable the FDA to mandate changes to labels of FDA-approved products if a new risk is discovered. HR 2090 has been referred to the House Committee on Energy and Commerce.

## **7) Support & Opposition.**

Support: American Federation of State, County and Municipal Employees

California Alliance for Retired Americans

California Labor Federation

California Psychological Association

California Public Interest Research Group

Congress of California Seniors

Consumers Union

Greenlining Institute

Health Access California

Protection and Advocacy, Inc.

Opposition: American College of Obstetricians and Gynecologists, Region IX

California Hospital Association

California Medical Association

California Society of Health-System Pharmacists

Kaiser Permanente

## **8) History.**

2005

June 29 From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 7. Noes 0.) Re-referred to Com. on APPR.

June 21 From committee with author's amendments. Read second time. Amended. Re-referred to committee.

June 15 From committee: Do pass, but first be re-referred to Com. on B. & P. (Ayes 9. Noes 4.) Re-referred to Com. on B. & P.

June 7 Set, first hearing. Hearing canceled at the request of author.

May 26 To Coms. on HEALTH and B. & P.

May 2 In Assembly. Read first time. Held at Desk.

May 2 Read third time. Passed. (Ayes 23. Noes 13. Page 867.) To Assembly.

Apr. 28 Read second time. Amended. To third reading.

Apr. 27 From committee: Do pass as amended. (Ayes 9. Noes 2. Page 767.)

Apr. 18 Set for hearing April 25.

Apr. 11 Read second time. Amended. Re-referred to Com. on APPR.

Apr. 7 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 7. Noes 3. Page 411.)

Mar. 14 Set for hearing March 30.

Feb. 24 To Com. on HEALTH.

Feb. 18 From print. May be acted upon on or after March 20.

Feb. 17 Introduced. Read first time. To Com. on RLS. for assignment. To print.

# 2006 Legislative Session Calendar

## January 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

- Jan. 4** Legislature reconvenes.
- Jan. 10** Budget must be submitted by Governor.
- Jan. 13** Last day for policy committees to hear bills introduced in their house in 2005.
- Jan. 31** Last day for each house to pass bills introduced in 2005 in their house.

## February 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28				

- Feb. 24** Last day for bills to be introduced.

## March 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

# 2006 Legislative Session Calendar

## April 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
30						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29

**April 6-16** Spring Recess.

**April 17** Legislature reconvenes.

## May 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

**May 30 – June 2** Floor session only.

## June 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

**June 2** Last day for bills to be passed out of the house of origin.

**June 15** Budget must be passed by midnight.

**June 30** Last day for policy committees to meet and report bills.



# 2006 Legislative Session Calendar

## July 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
30	31					1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29

July 7 Aug. 6 Summer Recess.

## August 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

Aug. 7 Legislature reconvenes.

Aug. 18 Last day for fiscal committees to meet and report bills to floor.

Aug. 21-31 Floor session only.

Aug 31. Final recess begins at end of this day's session.

## September 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

Sep. 30 Last day for Governor to sign or veto bills passed by the Legislature.

Dec. 4, 2006, 2007-08 Legislative Session Convenes.

**Strategic Plan Status Report**  
**Second Quarter 2005/2006**  
October 1, 2005 thru December 31, 2005  
**Legislation and Regulation Committee**

<b>Goal 3:</b>	<p><b>Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.</b></p> <p><b>Outcome:</b> Improve the health and safety of Californians.</p>
<b>Objective 3.1:</b>	<p><b>Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.</b></p> <p><b>Measure:</b> 100 percent successful enactment of promoted legislative changes.</p>
<b>Tasks:</b>	<ol style="list-style-type: none"> <li>1. Secure extension of board's sunset date. <ul style="list-style-type: none"> <li>▪ <b>Completed September 25, 2003 - Chapter 539, Statutes of 2003 (SB 361)</b></li> </ul> </li> <li>2. Sponsor legislation to strengthen and update licensing requirements for pharmacy technicians. <ul style="list-style-type: none"> <li>▪ <b>Completed September 25, 2003 - Chapter 539, Statutes of 2003 (SB 361)</b></li> </ul> </li> <li>3. Sponsor legislation to add enforcement options for non-compliance issues. <ul style="list-style-type: none"> <li>▪ <b>Completed September 25, 2003 - Chapter 539, Statutes of 2003 (SB 361)</b></li> </ul> </li> <li>4. Sponsor legislation to update pharmacy law to standardize terminology regarding cancellation of licenses, waiving pharmacy law requirements during declared emergencies. <ul style="list-style-type: none"> <li>▪ <b>Completed September 25, 2003 - Chapter 539, Statutes of 2003 (SB 361)</b></li> </ul> </li> <li>5. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices. <ul style="list-style-type: none"> <li>▪ <b><u>Advocacy:</u> AB 320, AB 1826, AB 1960, AB 2184, AB 2660, AB 2682, SB 1159, AB 1196, SB 1427, SB 1563, SB 1735, SB 151, SB 175, SB 361, SB 490, SB 545, SB 774</b></li> <li>▪ <b><u>Technical Assistance:</u> AB 262, AB 746, AB 1196, AB 1957, AB 2125, SB 151, SB 175, SB 292, SB 361, SB 490, SB 545, SB 774, SB 907, SB 1149, SB 1333</b></li> </ul> </li> <li>6. Sponsor clean-up language to B &amp; P Code section 4312. <ul style="list-style-type: none"> <li>▪ <b>Completed September 25, 2003 - Chapter 539, Statutes of 2003 (SB 361)</b></li> </ul> </li> <li>7. Sponsor public meetings 4 times a year to solicit comments on areas needing legislative changes. <ul style="list-style-type: none"> <li>▪ <b>Public meetings held on March 27, 2003 and September 11, 2003.</b></li> <li>▪ <b>Public meeting held on March 30, 2004.</b></li> <li>▪ <b>Public meeting held on October 25, 2005.</b></li> </ul> </li> <li>8. Sponsor legislation to strengthen consumer protections in wholesale transactions. <ul style="list-style-type: none"> <li>▪ <b>Completed 9/29/2004 – Chapters 857 and 887, Statutes of 2004.</b></li> </ul> </li> <li>9. Sponsor legislation to address licensing issues related to the UC Davis Veterinary Medical Teaching Hospital. <ul style="list-style-type: none"> <li>▪ <b>Governor signed SB 1913 September 22, 2004.</b></li> </ul> </li> <li>10. Sponsor legislation to define "compounding and establish standards for pharmacies that compound drug products for patients. <ul style="list-style-type: none"> <li>▪ <b>AB 595 (Negrete McLeod) Pharmacy: Compounding of Prescription Drugs. Introduced February 17, 2005.</b></li> </ul> </li> </ol>

	<p>11. Support for Senate B&amp;P Committee Omnibus bill that includes changes to the following code sections:</p> <ul style="list-style-type: none"> <li>▪ <b>B&amp;P 4005 &amp; 4206, 4053, 4127.5, 4205 &amp; 4400, 4231 &amp; 4232, 4360-4373, 4023.5, 4038, 4114, 4115, 4115.5 &amp; 4202, 4315, 4104</b></li> <li>▪ <b>SB 1111 (B&amp;P Com.) Omnibus Bill. Chapter 621, Statutes of 2005.</b></li> </ul>
<b>Objective 3.2:</b>	<p><b>Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.</b></p> <p><b>Measure:</b> Percentage successful enactment of promoted regulatory changes.</p>
<b>Tasks:</b>	<ol style="list-style-type: none"> <li>1. Strengthen standards for compounding sterile injectable drug products. <ul style="list-style-type: none"> <li>▪ <b>Completed. Regulation effective October 29, 2004.</b></li> </ul> </li> <li>2. Authorize the executive officer the authority to issue citations and fines. <ul style="list-style-type: none"> <li>▪ <b>Completed. Regulation effective October 11, 2003.</b></li> </ul> </li> <li>3. Eliminate the clerk typist ratio. <ul style="list-style-type: none"> <li>▪ <b>Completed. Regulation effective October 3, 2004.</b></li> </ul> </li> <li>4. Allow pharmacists to be pharmacist-in-charge of two locations simultaneously. <ul style="list-style-type: none"> <li>▪ <b>Completed. Regulation effective October 2, 2004.</b></li> </ul> </li> <li>5. Update pharmacy self-assessment form. <ul style="list-style-type: none"> <li>▪ <b>January 2005 – Board adopted</b></li> </ul> </li> <li>6. Allow central filling by hospital pharmacies. <ul style="list-style-type: none"> <li>▪ <b>Completed. Regulation effective October 22, 2004.</b></li> </ul> </li> <li>7. Revise regulations concerning electronic prescribing to conform to AB 2245, and require that the pharmacist confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity. <ul style="list-style-type: none"> <li>▪ <b>Completed. Regulation effective October 22, 2004.</b></li> </ul> </li> <li>8. Modify patient notification provision of the quality assurance regulation to require notification only if the error results in the medication being administered to the patient or a clinically significant delay in therapy. <ul style="list-style-type: none"> <li>▪ <b>Completed. Regulation effective October 22, 2004.</b></li> </ul> </li> <li>9. Require pharmacies using a common electronic file to adopt policies to ensure confidentiality of patient information. <ul style="list-style-type: none"> <li>▪ <b>Completed. Regulation effective October 22, 2004.</b></li> </ul> </li> <li>10. Update pharmacy technician regulations to conform to SB 361. <ul style="list-style-type: none"> <li>▪ <b>Completed. Regulation effective October 22, 2004.</b></li> </ul> </li> <li>11. Update pharmacist licensure regulations to conform to SB 361. <ul style="list-style-type: none"> <li>▪ <b>Completed. Regulation effective October 22, 2004.</b></li> </ul> </li> <li>12. Complete a Section 100 filing to clean up regulations in conformity with recent legislation.</li> <li>13. Omnibus rule making package covering the following areas: abandonment of application files, pharmacist identification, pharmacy self assessment, pharmacy practice, recognized schools of pharmacy, application of pharmacist examination and licensure, supervision of intern pharmacists, intern pharmacist, requirements for examination, pharmacist candidates, continuing education, fees, partial filling of schedule II prescriptions, foreign graduates. <ul style="list-style-type: none"> <li>▪ <b>Completed. Regulation effective October 7, 2005.</b></li> </ul> </li> <li>14. Revise regulations regarding the posting of posting of intern pharmacist addresses on the Board's Web site. <ul style="list-style-type: none"> <li>▪ <b>Regulation noticed on August 16, 2005.</b></li> </ul> </li> <li>15. Allow the use of automated dispensing devices to dispense refill prescriptions. <ul style="list-style-type: none"> <li>▪ <b>Regulation noticed on August 16, 2005.</b></li> </ul> </li> </ol>

	<p>16. Permit the use of drop boxes to drop off prescriptions.</p> <ul style="list-style-type: none"> <li>▪ <b>Regulation noticed on August 16, 2005.</b></li> </ul> <p>17. Create wholesaler surety bond forms.</p> <ul style="list-style-type: none"> <li>▪ OAL Approved \$100,000 bond form in December 2005</li> <li>▪ OAL Approved \$25,000 bond form on January 24, 2006</li> </ul>
<b>Objective 3.3:</b>	<p><b>Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2005.</b></p> <p><b>Measure:</b> Number of areas of pharmacy law reviewed.</p>
<b>Tasks:</b>	<ol style="list-style-type: none"> <li>1. Evaluate electronic prescribing laws involving controlled substances.</li> <li>2. Evaluate the prescribing and dispensing of veterinary drugs. <ul style="list-style-type: none"> <li>▪ <b>Completed – Chapter 250, Statutes of 2003 (SB 175)</b></li> </ul> </li> <li>3. Evaluate group dispensing by prescribers. <ul style="list-style-type: none"> <li>▪ <b>August 2003</b> - Draft legislation developed in concert with the Medical Board. Awaiting board action.</li> </ul> </li> <li>4. Evaluate pharmacist intern statutes and regulations. <ul style="list-style-type: none"> <li>▪ <b>December 2003</b> – Draft legislation and regulations prepared and presented to the Licensing Committee.</li> <li>▪ <b>January 2004</b> – Draft legislation and regulations approved by the board.</li> <li>▪ <b>February 2004</b> – Rulemaking noticed on approved regulations.</li> <li>▪ <b>March 2004</b> – Statutory provisions introduced in SB 1913. Governor signed SB 1913 on September 22, 2004.</li> </ul> </li> <li>5. Evaluated out of state distributor requirements. <ul style="list-style-type: none"> <li>▪ <b>Completed – Chapter 725, Statutes of 2004 (AB 2628)</b></li> <li>▪ <b>Completed – Chapter 857, Statutes of 2004 (SB 1307)</b></li> </ul> </li> <li>6. Evaluated clinic licensing. <ul style="list-style-type: none"> <li>▪ <b>March 2005</b> – Initiated.</li> <li>▪ <b>October 2005</b> - Draft legislation prepared and presented to the Legislation and Regulation Committee</li> </ul> </li> </ol>